In 3/2

INFANT FORMULA ACT OF 1980

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

NINETY-SIXTH CONGRESS

SECOND SESSION

ON

S. 2490

TO PROVIDE CERTAIN REQUIREMENTS FOR INFANT FORMULA, AND FOR OTHER PURPOSES

JUNE 12, 1980

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INFANT FORMULA ACT OF 1980

THURSDAY, JUNE 12, 1980

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 4232, Dirksen Senate Office Building, Senator Howard M. Metzenbaum, presiding pro tempore.

Present: Senators Metzenbaum, Schweiker, and Hatch.

OPENING STATEMENT OF SENATOR METZENBAUM

Senator METZENBAUM. The Subcommittee on Health and Scientific Research will hear testimony on the Infant Formula Act of 1980, a bill that I introduced in March of this year with the cosponsorship of Senators Baucus, Leahy, Huddleston, McGovern, and Moynihan. A similar measure has been offered in the House.

This legislation has a simple and straightforward purpose, which is to assure the parents of this country that the infant formula they purchase will be safe for their children to consume.

I believe that parents have a right to be able to take for granted that the highest standards of quality control will be used in the production of infant formula. And it goes without saying that formula must meet all of an infant's nutritional needs. But unfortunately, these obvious requirements have not always been met.

Recently, we have seen not one but four formula products recalled—Neo-Mull-Soy, Cho-Free, and Soyalac because they lacked chloride, an essential nutrient. And S.M.A, another product, was recalled because of poor processing.

In addition, we have seen that the FDA was slow in ordering a recall. And when the recall order was finally issued, it was so lax that Neo-Mull-Soy was still on some pharmacy shelves 2 full months after the recall.

The failure of a recall in and of itself is reason enough for concern. But to my mind failure to recall a product that provides, in many cases, the sole source of food for newborn infants during the all-important and formative first 6 months of life is inexcusable.

This failure is even more infuriating in the case of "Neo-Mull-Soy" since adulteration could easily have been prevented by requiring that minimum nutritional standards be met before the product could be marketed. Currently, FDA has no such requirements.

The legislation that we will consider today is intended to solve these problems by directing the Secretary of Health and Human Services to establish nutrient requirements and standards for

proper manufacturing practices for infant formula. The bill establishes guidelines for premarketing laboratory tests and directs processors to notify the FDA if any product is found to be adulterated or misbranded.

The bill also gives the FDA the authority to inspect manufacturing records, establishes guidelines for labeling of formula products, and prohibits the export of adulterated or misbranded formula.

[The text of S. 2490 and H. Rept. 96-936 follows:]

II

96TH CONGRESS
2D SESSION

S. 2490

To provide certain requirements for infant formula, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 27 (legislative day, JANUARY 3), 1980

Mr. METZENBAUM (for himself, Mr. BAUCUS, and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

---

A BILL

To provide certain requirements for infant formula, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Infant Formula Act of 1980".

SEC. 2. (a) Section 201 is amended by adding the following new subsection at the end thereof:

"(aa) For purposes of this section, the term 'infant formula' means a food that purports to be or is represented for special dietary use solely as a food for infants by reason of its

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simulation of human milk or its suitability as a complete or partial substitute for human milk.".

(b) Section 301 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new subsections:

"(s) The violation of any requirement provided under section 412 with respect to infant formula, including the failure to meet the standards required pursuant to section 412(a), the failure to submit reports or test results in accordance with section 412(b), the failure to make any notification required by section 412(c), and the failure to make or retain records or make reports in accordance with section 412(d).

"(t) The movement of food in violation of an order under section 412(e) or the removal or alteration of any mark or label required by such order to identify the food as detained.".

(c) Section 301(e) of the Federal Food, Drug, and Cosmetic Act is amended—

(1) by striking out "section 703" and inserting in lieu thereof "section 412(d) or 703"; and

(2) by striking out "section 505" and inserting in lieu thereof "section 412(d), 505".

(d) Section 402 of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new paragraph at the end thereof:

"(f) If it purports to be or is represented to be an infant formula unless it complies with the regulations promulgated by the Secretary relating to required standards of identity and quality including required levels of nutrients pursuant to section 412(a).".

(e) Section 403 of the Federal Food, Drug, and Cosmetic Act is amended by inserting the following new paragraph at the end thereof:

"(q) If it purports to be or is represented to be an infant formula unless the package or other container in which such infant formula is contained is labeled in accordance with section 412(h).".

(f) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new section at the end thereof:

"REQUIREMENTS REGARDING INFANT FORMULA

"SEC. 412. (a)(1) The Secretary shall promulgate regulations fixing and establishing for infant formula a reasonable definition and standards of identity and quality, including the required nutrients at minimum and maximum levels.

"(2) The Secretary may by regulation exempt from the requirements of this subsection any infant formula that is for use by—

"(A) any infant diagnosed by a physician or other appropriate health professional as having certain inborn errors of metabolism; or

"(B) any infant having unusual medical or dietary problems.

"(b)(1) Not later than the date one hundred and eighty days after the date of the enactment of this section and annually thereafter, each processor of an infant formula shall submit to the Secretary reports or test results that show satisfactorily that the infant formula processed by such processor meets the requirements prescribed by the Secretary pursuant to subsection (a).

"(2)(A) Not later than the date ninety days before the date of the first processing for commercial purposes of an infant formula, the processor shall submit to the Secretary reports or test results that show satisfactorily that such infant formula meets the requirements prescribed pursuant to subsection (a).

"(B) For purposes of this paragraph, if the formulation or processing of an infant formula is changed, the date of the first renewed processing of such infant formula following such change shall be considered to be within the meaning of the term 'the date of the first processing for commercial purposes of an infant formula'.

"(c)(1) If a processor acquires information indicating that any infant formula processed by such processor may be adulterated within the meaning of section 402(f), or misbranded within the meaning of section 403(q), and that such infant formula is no longer located at an establishment subject to the control of such processor, and such processor has not promptly determined, after a reasonable opportunity to investigate the information, that such information is incorrect, such processor shall promptly notify the Secretary, in such form and manner as may be prescribed by the Secretary, of such information.

"(2) If a processor institutes a recall of an infant formula processed by such processor because such processor has reason to believe the infant formula may be adulterated within the meaning of section 402(f), or misbranded within the meaning of section 403(q), and such infant formula is no longer located at an establishment subject to the control of such processor, such processor shall notify the Secretary immediately, in such form and manner as may be prescribed by the Secretary, of such recall.

"(3) Information required to be contained in a notification provided to the Secretary pursuant to paragraph (1) may not be introduced as evidence in any proceeding against such person under section 303 with regard to a violation of section 301 (s) or (t).

"(d)(1) Each processor of an infant formula shall—

"(A) make and retain such records respecting the distribution of the infant formula at any establishment owned or operated by such processor as may be necessary, as determined by the Secretary, to effect and monitor recalls of the formula and to otherwise trace the distribution of the formula; and

"(B) make such records available to the Secretary (or to a duly authorized representative of the Secretary) for examination and copying on or off the premises of such processor.

No processor shall be required under this subsection to retain any record respecting the distribution of an infant formula for a period of longer than two years from the date the record was made.

"(2) Each manufacturer of an infant formula shall maintain such records respecting the manufacturing of the infant formula and shall make such reports as the Secretary may reasonably require to assure compliance with the requirements of subsection (a).

"(e)(1) If during an inspection conducted under section 704 of a facility or a vehicle, an infant formula that the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the infant formula

detained (in accordance with regulations prescribed by the Secretary) for a reasonable period not to exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under section 302 or section 304(a) of this Act, in which case the Secretary may authorize a detention period of not to exceed thirty days. A detention order under this paragraph may require the labeling or marking of an infant formula during the period of such detention for the purpose of identifying the product as detained. Any person entitled to claim such infant formula if it was seized under section 304(a) of this Act may appeal to the Secretary a detention of such formula under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary (or within such other period as may be mutually agreed upon by the Secretary and the person bringing the appeal), the Secretary shall, after affording opportunity for an informal hearing, by order confirm or revoke the detention.

"(2)(A) Except as authorized by subparagraph (B), an infant formula subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

"(i) such formula is released by the Secretary, or

"(ii) the detention period applicable to such order has expired,

whichever occurs first.

"(B) An infant formula subject to a detention order under paragraph (1) may be moved in accordance with regulations prescribed by the Secretary.

"(f) An officer or employee making an inspection under section 704 for purposes of enforcing the requirements of this section shall be permitted, at all reasonable times, to have access to and to copy and verify any records (other than records of financial data, sales data other than shipment data, pricing data, and personnel data other than information as to the qualifications and responsibilities of technical, professional, and supervisory personnel performing functions relating to infant formulas subject to this section)—

"(1) regarding whether the infant formula processed or held in the facility inspected meets the requirements of subsection (a); or

"(2) required to be maintained under subsection (e).

"(g)(1) Each processor of infant formula shall prepare, in compliance with paragraph (2), information labeling for users respecting such product. Each such processor shall distribute such labeling to accompany the product.

"(2) Information labeling of infant formula shall contain—

"(A) a summary of the benefits and risks associated with the use of such product including an endorsement of breast feeding as the method of first choice unless otherwise advised by a physician;

"(B) adequate directions for use, including—

"(i) the purposes or indications for which the product is intended,

"(ii) the proper method of administration of the product including—

"(I) labels distinguished by color to indicate ready-to-feed, concentrate, or powder mix, and

"(II) clear written and pictorial instructions for proper use,

"(iii) precautions to be taken during the use of the product, and side effects and adverse reactions that may result from the improper use of the product, as well as instructions for recognizing, treating, or obtaining treatment for side effects and adverse reactions, and

"(iv) warnings against unsafe use of the product; and

"(C) information concerning the proper storage and handling of the product.

"(3) Any word, statement, or other information required under this subsection to appear on any labeling of infant formula shall be prominently and conspicuously placed on the labeling (compared with other words, statements, designs, or graphic matter in the labeling) and shall be in terms that render such information likely to be read and understood by the ordinary individual who would reasonably be expected to see the labeling.

"(h) With respect to an infant formula, the processor shall prepare information labeling for practitioners whenever such product is provided to practitioners or health care facilities for use or dispensing, and shall distribute such labeling to accompany the product. Information labeling for practitioners shall contain adequate directions for and other information concerning use of the product, including information regarding the risks and benefits of breast feeding, indications, administration, contraindications to use, warnings, precautions, and side effects, so as to permit the dispensing or administration of the product in a manner that promotes the safe use of the product.

"(i) No provision of this section which relates to labeling shall be construed to alter the provisions of existing law governing the tort liability of any person.

"(j) A formula product for infants may not be exported unless—

"(1) such product is not adulterated within the meaning of section 402(f);

"(2) the labeling of such product meets the requirements of subsection (g) in the language specified by the foreign purchaser; and

"(3) such product is not in conflict with the laws of the country to which it is intended for export.".

(g) Subsection (a) of section 412 of the Federal Food, Drug, and Cosmetic Act shall apply with respect to infant formulas introduced or delivered for introduction into interstate commerce on or after the date ninety days after the date of the enactment of this Act.

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96TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 96-936

INFANT FORMULA ACT OF 1980

REPORT

BY THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

[To accompany H.R. 6940]

[And including cost estimate of the Congressional Budget Office]

MAY 12, 1980.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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WASHINGTON: 1980

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96TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 96-936

INFANT FORMULA ACT OF 1980

MAY 12, 1980.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 6940]

[Including cost estimate of the Congressional Budget Office]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 6940) to amend the Federal Food, Drug, and Cosmetic Act to strengthen the authority under that act to assure the safety and nutrition of infant formulas, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments (stated in terms of the page and line numbers of the introduced bill) are as follows:

Page 2, strike out line 20 and insert in lieu thereof the following:

subparagraph (C) and establish requirements respecting the retention of records of procedures required under this subparagraph".

Page 3, strike out line 19 and all that follows through line 4 on page 4 and insert the following:

(c)(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

(A) may not be in compliance with the requirements of subsection (a)(1)(A), or

(B)(i) may be otherwise adulterated or misbranded, and

(ii) if so adulterated or misbranded presents a risk to human health,

the manufacturer shall promptly notify the Secretary of such noncompliance or risk to health.

(2) For purposes of paragraph (1), the term "knowledge" as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

Page 8, line 20, strike out "(e)".

Page 9, line 5, strike out "(e)" and in line 6 on that page strike out "(e)".

Page 9, insert after line 12 the following:

SEC. 7. The Secretary of Health and Human Services shall conduct a study to determine the long-term effect on infants of hypochloremic metabolic alkalosis resulting from infant formulas deficient in chloride. The Secretary shall report the results of such study to the Congress.

SEC. 8. (a) Section 503 of the Controlled Substances Act (21 U.S.C. 873) is amended by adding at the end the following new subsection:

"(c) The Attorney General shall annually (1) select the controlled substance (or controlled substances) contained in schedule II which the Attorney General, in his discretion, determines to have the highest rate of abuse, and (2) prepare and make available to regulatory, licensing, and law enforcement agencies of States descriptive and analytic reports on the actual distribution patterns in such States of each such controlled substance.".

(b) Section 203 of the Psychotropic Substances Act of 1978 (Public Law 95-633) is amended by striking out subsection (d).

(c) Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended—

(1) by striking out "except as provided in paragraphs (4) and (5) of this subsection" in the first sentence of subsection (b)(1)(B) and inserting in lieu thereof "except as provided in paragraphs (4), (5), and (6) of this subsection"; and

(2) by adding after paragraph (5) of subsection (b) the following new paragraph:

"(6) In the case of a violation of subsection (a) involving a quantity of marihuana exceeding 1,000 pounds, such person shall be sentenced to a term of imprisonment of not more than fifteen years, and in addition, may be fined not more than $125,000. If any person commits such a violation after one or more prior convictions of him for an offense punishable under paragraph (1) of this paragraph, or for a felony under any other provision of this title, title III, or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than thirty years, and in addition, may be fined not more than $250,000.".

3

Amend the title so as to read:
A bill to amend the Federal Food, Drug, and Cosmetic Act to strengthen the authority under that Act to assure the safety and nutrition of infant formulas, and for other purposes.

Summary of Legislation

H.R. 6940 adds a new Section to Chapter IV of the Federal Food Drug and Cosmetic Act. The bill creates a separate category of food designated "infant formula" and requires that formula meet specified standards of quality and safety. The section provides authority for the Secretary of the Department of Health and Human Services to establish nutritional, quality control, record keeping, notification and recall requirements necessary to insure that infant formula is safe and will promote healthy growth. The legislation also provides the Secretary authority to inspect records and factory facilities necessary to monitor and effect formula recalls and to determine compliance with formula quality requirements.

In addition, the legislation would do the following:

1. Require the Secretary of the Department of Health and Human Services to conduct a comprehensive scientific study to ascertain the long term health effect on infants of hyprochloremic metabolic alkalosis. Hypochloremic metabolic alkalosis is an illness which affected infants who consumed a formula dangerously deficient in chloride.

2. Amend Section 503 of the Controlled Substances Act (21 U.S.C. 873) to require the Attorney General to provide state regulatory, licensing and law enforcement agencies annual descriptive and analytic reports on the distribution of schedule II controlled substances.

3. Amend Section 203 of the Psychotropic Substances Act of 1978 to continue indefinitely the distribution reporting requirements for the PCP precursor piperidine.

4. Amend Section 401 of the Controlled Substances Act (21 U.S.C. 841) to increase criminal penalties for trafficking in over 1,000 pounds of marihuana.

Cost of Legislation

The Committee does not anticipate that adoption of H.R. 6940 will require the authorization of additional appropriations. No additional appropriations are authorized to implement and administer authority contained in the bill. The Committee expects this authority to be administered through use of existing resources.

Legislative History

Several legislative proposals, to assure the safety and nutritional quality of infant formula, were introduced and referred to the Subcommittee on Health and the Environment. H.R. 5836, was introduced on November 8, 1979 by Mr. Gore. H.R. 5839 was introduced on November 8, 1979 by Mr. Mottl and Mr. Gore. H.R. 6590 was introduced on February 25, 1980 by Dr. Carter. H.R. 6608 was introduced on February 26, 1980 by Mr. Gore. Hearings on these proposals were conducted by the Subcommittee on Health and the Environment on

February 28 and March 6, 1980. On March 23, 1980 the subcommittee met to consider a subcommittee working draft reflecting a consolidation of the pending legislative proposals. The working draft was approved, without amendment, by unanimous voice vote of the Subcommittee and ordered reported as a clean bill. H.R. 6940, a bill reflecting the Subcommittee's action, was introduced on March 26, 1980 by Mr. Waxman, Mr. Gore, Mr. Mottl, Dr. Carter, Mr. Preyer, Mr. Maguire, Mr. Walgren, Ms. Mikulski, Mr. Gramm, Mr. Leland, Mr. Shelby and Mr. Murphy.

H.R. 6940 was considered by the Committee on April 16, 1980 and ordered reported, with amendments, by unanimous voice vote.

Similar legisaltion, S. 2490, was introduced in the Senate on March 27, 1980 and referred to the Committee on Labor and Human Resources.

Committee Proposal

Legislative Background

At present there are no Federal statutes or regulations which require that infant formula contain all nutrients recognized as essential. Current regulations pertaining to infant formula are limited to ingredient labeling and processing in sanitary facilities. Infant formula labeling regulations (21 CFR 105.65) were promulgated pursuant to sections 403 and 701 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343 and 371). Regulations respecting the processing of formula in sanitary facilities were promulgated pursuant to section 402(a)(3) and (4) of the Federal Food, Drug and Cosmetic Act.

Need For Legislation

Last summer, many Americans were stunned by reports that two infant formulas—Neo-Mull-Soy and Cho-Free—had been marketed which were critically deficient in chloride, a life sustaining nutrient. The conference of thousands of parents in the safety and quality of commercially prepared infant formulas was seriously shaken.

The aftermath of these events was truly tragic. Over 130 infants who had consumed the formula suffered injury from a potentially lethal and rare chemical imbalance in the blood known as hypochloremic metabolic alkalosis. Fortunately, no known deaths occurred although the long term effects of this injury on future growth and development are, as yet, unknown.

Upon learning these events, the Committee's Subcommittee on Oversight and Investigations conducted a vigorous and thorough examination of the circumstances which lead to the marketing of these nutritionally deficient formulas. The Subcommittee also examined the adequacy of existing nutrition composition requirements and the effectiveness of the Food and Drug Administration's efforts to effect a recall of the harmful products.

The Subcommittee developed information that the manufacturer of the chloride deficient formula failed to maintain adequate quality control procedures to insure the maintenance of vital ingredients prior to marketing. In addition, the Subcommittee discovered that existing

FDA infant formula regulations were outdated and may have contributed to the events which permitted the sale of the hazardous products. FDA regulations on infant formula had not been updated since 1971. FDA did not require chloride as a vital nutrient, although the 1976 recommendations of the American Academy of Pediatrics clearly specified chloride as a necessary ingredient in all infant formula products.

In addition, the Subcommittee determined that FDA efforts to effect a swift and complete recall of the chloride deficient formula were inadequate and permitted the formula to remain on the market three months after the recall was initiated. The effectiveness of the recall was further hampered by the failure of the manufacturer to cooperate fully with the FDA in the monitoring of recall activities.

Upon conclusion of the investigation, the Subcommittee prepared a report on its activities (Committee Print 96–IFC–42) and recommended that the Congress enact legislation to:

1. Create a separate category of food designated "infant formula", to include only those products that are intended to provide a nutritionally adequate diet to normal infants.
2. Require that infant formulas contain all nutrients recognized as essential.
3. Require that a product contain these essential nutrients before permitting the label, "infant formula".
4. Require that all infant formulas be tested for their nutritional adequacy before marketing and after any change in the manufacturing process.
5. Require that recalls of infant formula products be conducted as class I recalls, the FDA classification which recognizes a potential for serious adverse health consequences or death.
6. Grant FDA authority, in infant formula recall situations, to inspect a manufacturer's records and to enforce compliance with recall directives.
7. Require that 100 percent of consignees be contacted during monitoring of infant formula recalls, a procedure defined as a "Level A effectiveness check" by FDA.

The Committee recognizes that infant formulas are often the sole source of nutrition for tens of thousands of infants. The growth of infants during the first few months of life often determines the pattern of development and quality of health in adult life. More than any other food product, the public rightfully expects infant formula to be manufactured to exacting standards. The Committee believes the events of last summer are a stark warning that as a nation, we may have been too casual in our attitude toward infant nutrition. The availability of infant formula which is safe and nutritious is critically important to the health of our nation.

For parents to continue to have confidence in the quality of formula upon which their children depend, they must be assured that formula contains all essential nutrients and has been adequately tested prior to marketing. Mandatory Federal standards to assure the safety and quality of infant formula are in the public interest. The Committee believes the passage of H.R. 6940 will go far in restoring public confidence in the safety and nutritional quality of infant formula.

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Proposed Legislation

H.R. 6940 creates a new category of food called "infant formula" and provides authority for the Secretary of the Department of Health and Human Services to establish procedures and requirements necessary to insure safety and quality of the product.

NUTRITIONAL AND OTHER QUALITY FACTORS

Subsection (a) of the proposed Section 412 establishes standards for the content and processing of infant formula. Formula which does not contain required nutrients or which is not manufactured in accordance with prescribed quality control procedures would be deemed "adulterated" and its distribution prohibited.

Upon the effective date of the legislation, infant formulas intended for normal, full term infants will be required to contain all nutrients, in specified amounts and ratios, listed in the table contained in subsection 412(g). Subsection (g) establishes minimum and maximum formula nutrient levels.

The Committee has elected to specify an initial list of ingredients in the statute to insure that uniform standards for infant formula will be in place upon the effective date of the legislation. The Committee believes it would be irresponsible public policy to permit the effective establishment of formula safety and quality standards to be delayed one or two years due to the procedural requirements of the rule making process. The ingredients specified in subsection (g) reflect a carefully studied and time tested consensus on the part of the infant formula industry and the medical and scientific community.

The Committee recognizes, however, that scientific and medical understanding of the nutrients necessary for proper infant nutrition is constantly expanding. The Committee bill establishes levels for those nutrients which we now know are necessary but does not provide for those nutrients which may be found to be essential in the future.

The Committee believes the infant formula ingredient standard should be flexible enough to permit timely modification. Paragraph 412(a)(2) of the bill provides the Secretary authority to add, subtract or revise by regulation nutrients specified in the table.

Prior to such modification, the addition of a nutrient to a formula which is not included in the table would not cause a formula to become adulterated unless such nutrient or ingredient is a "poisonous or deleterious substance" under Section 402(a) of the Federal Food, Drug and Cosmetic Act. The Committee expects the Secretary to move expeditiously to initiate regulatory procedures to revise the ingredient table to reflect changes in knowledge about infant nutrition.

In addition to the requirements for certain nutrients, subsection (a)(2) provides authority for the Secretary to require that formula nutrients contain certain quality factors and that the formula be manufactured in accordance with effective quality control procedures. Quality factors pertain to the bioavailability of a nutrient and the maintenance of level or potency of nutrients during the expected shelf life of the product. Quality control procedures are those procedures which would assure proper manufacturing of the formula products.

Quality control procedures are not limited to those "good manufacturing practices" applicable to food products. Quality control procedures are intended to insure that the safety and nutritional potency of a formula is built into the manufacturing process. This authority is necessary as the absence of effective quality control mechanisms was a major factor in the production and subsequent sale last year of two formula products critically deficient in chloride. Existing statutory authority in this area is inadequate as it is limited to assurances that infant formula is filth free and is processed in a sanitary facility.

Premarket Testing Requirements

Subsection (b) of Section 412 sets forth two circumstances when a formula manufacturer must notify the Secretary, prior to marketing, that its formula is in compliance with the nutritional and other quality factors required by subsection (a).

In the first instance, a manufacturer must notify the Secretary 90 days prior to the marketing of a new infant formula. A new formula product is one which has not previously been processed for public distribution or a product whose formulation has not previously been produced by a given manufacturer.

In the second, a manufacturer must notify the Secretary at any time before the marketing of a formula which has had a change in formulation or processing. A change in formulation or processing is an action which the manufacturer reasonably determines may affect whether the formula is in compliance with required nutrient standards.

The Committee tied notification to the first "processing" of a formula for "commercial or charitable distribution". The Committee does not intend for notice to be provided when a manufacturer processes formula for research activities involving clinical testing with infants. Such clinical trials are part of a manufacturer's research program and are conducted prior to a decision to begin processing for commercial or charitable distribution.

Subsection (b) does not authorize any form of preclearance by the Food and Drug Administration for the marketing of an infant formula. No manufacturer need receive permission, clearance or approval to market a formula product upon submission of formal notification to the FDA and expiration of, in the case of new formulas, the required 90 days waiting period.

The Committee believes subsection (b) is an integral part of the regulatory strategy proposed by H.R. 6940. The provisions of subsection (b) are designed to insure against a recurrence of the earlier problems involving the marketing of nutrient deficient formula products. During 1979, the Committee learned of three episodes in which a manufacturer permitted a formula to be marketed—following a change in formulation or processing—without adequate testing. Notification to the Secretary will provide assurance that adequate tests have been conducted to insure compliance with subsection (a) and that the test results are available for review and verification.

The notification requirement contained in this subsection will go far to assure consumers a reasonable standard of safety while not unreasonably burdening the industry through a potentially cumbersome system of premarket clearances.

8

NOTIFICATION

Section 412(c) of the legislation requires a manufacturer to promptly notify the Secretary if it has knowledge which "reasonably supports the conclusion" that one of the manufacturer's infant formulas (1) may not be in compliance with the nutritional requirements specified in Section 412(a)(1)(A) or (2) may be otherwise adulterated or misbranded and as such presents a potential risk to human health. Failure to provide prompt notification is a prohibited act under Section 301 of the Federal Food, Drug and Cosmetic Act and is subject to criminal and civil penalties.

The purpose of this notification requirement is to provide the Secretary reasonable and timely opportunity to conduct an assessment of any potential health risk resulting from or associated with the use of an infant formula. The type of health risks, referred to in subsection 412(c)(1)(B), which the Committee is concerned about and which should be reported includes chronic and acute injury or illness associated with contamination due to improper manufacturing practices.

Although mandatory reporting of potential health risks will be a new responsibility for the infant formula industry, it is not new to American business. Pursuant to other Federal consumer protection statutes, manufacturers of thousands of products—automobiles, x-ray equipment, televisions, power saws—are currently subject to similar reporting requirements. For example, the Consumer Product Safety Act, the Motor Vehicle Safety Act and the Radiation Control for Health and Safety Act contain notification provisions similar to section 412(c). The Committee believes the protections provided consumers of infant formula should at least be equivalent to that already available to purchasers of toaster ovens and automobiles.

Under subsection (c)(1)(B), a manufacturer must notify the Secretary as soon as it acquires knowledge from which a reasonable person would conclude that a formula is adulterated or misbranded and presents a potential health risk to infants. The manufacturer's knowledge would include not only the information the manufacturer actually has but also any information a reasonable person would have under like circumstances or could have obtained upon the exercise of due care.

The Committee established a standard of reasonableness for compliance with and enforcement of this subsection. A manufacturer would be presumed to have any relevant information which a reasonable person would have or could obtain exercising due care. The manufacturer's determination of whether its product was in compliance with subsection (a), or was not otherwise adulterated or misbranded and did not present a risk to human health would be based on that information. A notice of noncompliance or risk to health would be required only if a reasonable person would conclude from the information that the infant formula in question is not in compliance or does present a risk to human health.

In enforcing this subsection, the Food and Drug Administration would evaluate a manufacturer's decision not to notify the Secretary based upon (a) the information which the manufacturer had, or should have had had it acted reasonably and with due care at the time it made its decision and (b) whether a reasonable person would have concluded from that information that the manufacturer's formula was not in

compliance or did present a risk to human health. The FDA would also evaluate the timeliness of a manufacturer's decision to notify the Secretary based upon (a) the information which the manufacturer had, or should have had if it acted reasonably and with due care, at the time it made its decision and (b) whether a reasonable person would have concluded from that information that the manufacturer's formula was not in compliance or did present a risk.

Infant Formula Recall Procedures

At present, the Secretary has no authority to order recalls. The decision by the manufacturer to recall its products and the scope of such recall are the result of negotiations between the manufacturer and the Food and Drug Administration (FDA). In view of the special nature of infant formula, the Committee believes the Secretary, acting through the FDA, should play a more active role in insuring the effectiveness of recalls involving these life sustaining products.

Under section 412(d)(1) of the Committee's bill, if a manufacturer initiates a recall of an infant formula, the recall must be carried out in accordance with requirements prescribed by the Secretary. The Secretary is authorized to prescribe the scope and extent of infant formula recalls, varying the requirements depending upon the degree of risk to human health presented by the formula subject to recall.

The Committee's bill further specifies a time limit of 15 days after the beginning of a recall and every 15 days thereafter until the recall is terminated, for the Secretary to review the manufacturer's compliance with the regulations. Similarly, the manufacturer would report to the Secretary within 14 days after the beginning of such recall and at least every 14 days thereafter, on actions taken to implement the recall.

The Committee believes that the events of last summer indicate the necessity of these requirements. Two chloride deficient formulas were available three months after recalls had been initiated. To avoid this situation in the future, the Committee requires FDA to play a more active role in monitoring and insuring the compliance of a manufacturer with the recall procedures. Failure by a manufacturer to comply with regulations prescribing a recall is a prohibited act under section 301 of the Federal Food, Drug and Cosmetic Act.

The Committee recognizes that every recall will differ in its scope and extent and that it would be therefore impossible to provide, by regulation, comprehensive requirements for every aspect of a formula recall. The Committee expects the FDA to develop necessary flexibility into their regulations to permit the tailoring of recall requirements to the appropriate degree of risk.

Access to Distribution Records

Subsection (e) of the new section 412 would require a manufacturer to make and retain distribution records and would provide authority for the Secretary to inspect those records. The purpose of such inspection authority is to improve the monitoring and effectiveness of infant formula recalls.

An essential factor in monitoring any recall is knowledge of the actual distribution of the affected products. At present, manufacturers

of infant formula are under no obligation to make records, respecting the distribution of their products, available to the Secretary. The Committee believes access to a manufacturer's distribution records would significantly improve the effectiveness of infant formula recalls. Such authority is needed to allow the Secretary, through direct contact with distributors, to determine the adequacy of a firm's recall procedures and the completeness of a firm's effectiveness checks.

SPECIAL FORMULAS

Subsection (f)(1) of Section 412 provides that formulas, represented and labeled for use by infants with (1) an inborn error of metabolism or low birth weight, or (2) who otherwise have an unusual medical or dietary problem, are exempt from the requirements of subsection (a), (b) and (c)(1). This exemption would take effect upon the effective date of this legislation. Thereafter, pursuant to subsection 412(f)(2), the Secretary could establish, by regulation, the precise terms and conditions for continuing the exemption.

The Committee recognizes that infants suffering from special medical disorders, such as phenylketonuria, or severe kidney diseases, require formulas tailored specifically to their medical needs. The Committee recognizes the need to exempt these formulas from the nutritional standards applicable to formulas intended for normal, full term infants.

The Committee concurs with the recommendations of the American Academy of Pediatrics' Committee on Nutrition that such special formulas be clearly labeled for the intended use and be accompanied by label inserts containing information, understandable to the parent, about the indications and use of the product. Accordingly, section 412(f)(1) requires that these special formulas be properly "represented and labeled for use."

Subsection (f)(2) provides authority for the Secretary to establish, by regulation, the terms and conditions for the exemption of an infant formula from subsections (a) and (b). The Committee recognizes the need to make special formulas available without the imposition of cumbersome regulations which may discourage formula manufacturers from committing resources into this vital public services. Conditions on exemptions promulgated under this authority should not make access to special formulas difficult. Instead, they should insure that such formulas are manufactured to the same high standards of quality required of formulas for normal infants. The Committee recognizes the importance of these products and the continued need to make them and new products like them, readily available to the public.

NUTRITIONAL REQUIREMENTS

Subsection (g) establishes a table of ingredients required in all infant formulas manufactured for normal, full term infants. The nutrients contained in the table reflect the 1976 recommendations of the American Academy of Pediatrics.

The Committee expects the Secretary to work closely with the American Academy of Pediatrics' Committee on Nutrition, the infant formula industry, the Codex Alimentarius Commission and others to

insure that the nutrient table is periodically revised to keep current with advances in knowledge about infant nutrition. Section 412(a)(2) of the bill provides authority for the Secretary to revise the table of ingredients by regulation.

The Committee wants to commend the American Academy of Pediatrics for its worldwide leadership in the development of quality standards for infant formula and notes that the Academy's Committee on Nutrition recently announced a series of proposed revisions in their 1976 recommendations. The Committee strongly urges the Secretary to carefully review the Committee on Nutrition's recommendations and proceed expeditiously to revise the nutrient table accordingly if such revisions are deemed appropriate.

FACTORY INSPECTION AUTHORITY

Section Four of the legislation provides authority for the Secretary to have access to facilities and records which bear on whether an infant formula manufactured or held in the facility meets the requirements of section 412.

Clause (2) of Section 4 extends the existing record exclusions contained in Section 704(a) of the Federal Food Drug and Cosmetic Act, to inspections regarding infant formula. No inspection, for the purpose of carrying out the authority of section 412, shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to the Act) and research data.

RESEARCH REPORT

Section Seven of the bill requires the Secretary to conduct a study and to report to the Congress on the long term health effects incurred by infants afflicted with hypochloremic metabolic alkalosis. The Committee expects the Secretary, acting through the National Institutes of Health and the Center for Disease Control, to conduct a lengthy study of infants injured by the consumption of formula deficient in chloride. The study should monitor the development of these children and determine whether any lasting health problems can be attributed to the formula they consumed.

Miscellaneous Provisions

DANGEROUS DRUG REPORTING

Section 8(a) of the bill amends Section 503 of the Controlled Substances Act (21 U.S.C. 873) to require the Attorney General to prepare and make available annually, reports on the distribution of selected controlled substances. Reports will pertain to those substances, subject to schedule II controls, which the Attorney General believes have the highest incidence of abuse. The reports are to be made available to state regulatory, licensing and law enforcement agencies in order to assist in their efforts to control the retail diversion of prescription medicines.

By definition, drugs subject to schedule II controls have (1) a currently accepted medical use, (2) may lead to severe psychological or

physical dependence and (3) a high potential for abuse. One requirement of all drugs or substances placed in this control category is that data on distribution be reported to the Drug Enforcement Administration's (DEA) Automation of Reports and Consolidated Orders System (ARCOS).

The Committee is impressed with the usefulness of ARCOS data in coordinating state drug enforcement, regulatory and licensing activities. The State of Wisconsin has made effective use of this material and the Committee intends the Attorney General, working through the DEA, to actively encourage other States to undertake such programs.

Although ARCOS data is currently made available to states, the Committee is disturbed by reports that data is not provided in a timely fashion nor in such form as to facilitate effective targeting of state diversion control activities.

The Committee believes the retail diversion of dangerous drugs is one of the most serious, and as yet underemphasized aspects of drug law enforcement. It is estimated by the Drug Enforcement Administration that between 80 and 90% of prescription medicines currently on the illicit street market are the result of retail diversion activities.

The Committee recognizes that drug abuse can no longer be defined solely in terms of illicit drugs like heroin or marihuana. Similarly, the effectiveness of drug enforcement activities cannot be fairly assessed without considering the emphasis given to control retail diversion. Drugs available only by prescription rank high on drug injury lists. Of the 10 drugs most associated with drug related injury, 6 are available by prescription.

Today, retail diversion is viewed as a state or local law enforcement responsibility. While the Committee agrees this is an appropriate division of responsibility, the Federal government has a vital interest in the development and success of state diversion control programs. Diversion control is a state and local responsibility, but drug abuse, the result of retail diversion activities, is very much a national problem.

The Committee believes that through vigorous and imaginative use of the ARCOS system, in conjunction with other drug diversion/abuse indicators such as the Drug Abuse Warning Network (DAWN), retail diversion activities can be identified and the individuals involved apprehended and prosecuted. States such as Wisconsin and Illinois have already demonstrated the effectiveness of such programs and the Committee believes the implementation of this subsection will encourage similar efforts in other states.

In the implementation of the annual reporting provision, the Committee expects the Attorney General to insure the allocation of additional analytical staff to the DEA's ARCOS program to provide the necessary evaluation of drug distribution patterns. In addition, the Attorney General should also insure the availability of sufficient program and computer support personnel to insure timely management and dissemination of ARCOS data.

PIPERIDINE REPORTING

Section 8(b) of the bill amends the Psychotropic Substance Act of 1978 (Public Law 95-633) to delete subsection (d) and continue in-

definitely the distribution reporting requirements for the PCP precursor piperidine. Subsection (d) of such Act provides that the reporting requirements would expire on January 1, 1980.

The abuse of and injuries associated with PCP continue to present a major public health threat. PCP is clearly one of the most dangerous and unpredictable drugs which today threaten our nation's youth. Piperidine is a chemical essential to the manufacture of PCP and the operation of clandestine PCP laboratories.

The Committee believes the piperidine reporting requirements have been useful to Federal law enforcement efforts to identify and crack down on the operation of clandestine PCP laboratories. Due in part to the effect of piperidine reporting, the supply of piperidine in legitimate distribution channels has decreased. In 1979, the number of PCP laboratories seized by the Drug Enforcement Administration decreased 35% from those seized in 1978.

The Committee believes piperidine reporting requirements have been successful and therefore strongly recommends they be continued.

MARIHUANA TRAFFICKING PENALTIES

Section 8(c) of the legislation increases maximum penalties for drug trafficking violations involving over 1,000 pounds of marihuana. The subsection amends section 401 of the Controlled Substances Act to distinguish—for purposes of criminal sanctions—between large and small trafficking violations.

The Committee proposal provides a harsh penalty for individuals convicted of trafficking in large amounts of marihuana. Individuals convicted of trafficking in over 1,000 pounds would be subject to a maximum 15 year prison sentence and/or a maximum $125,000 fine. Inidivduals convicted of a second offense would be subject to a maximum 30 year prison sentence and a maximum $250,000 fine.

Current law provides that individuals convicted of trafficking in marihuana, regardless of amount, are subject to a maximum 5 year prison sentence and/or a $15,000 fine. The penalties double in the case of convictions involving a second offense. Current law fails to distinguish between trafficking violations involving small versus large quantities of the drug.

The Committee believes the current drug penalty structure, with respect to marihuana, is inadequate to deter individuals and major criminal organizations involved in extensive trafficking operations. Law enforcement officials have testified repeatedly before the Committee that the financial benefits of large scale marihuana trafficking are so lucrative that current criminal sanctions are viewed as an acceptable cost of doing business.

The Committee believes the continued, indeed widespread illegal distribution of marihuana in the United States poses potentially grave public health ramifications. The Committee believes the widespread use of marihuana in America today is due in large measure to the activities of covert, sophisticated trafficking networks. If drug law enforcement personnel are to have an impact on reducing supplies of this drug, they must have the capability to recommend imposition of prison sentences sufficient to disrupt major trafficking operations.

The Committee amendment provides for maximum prison sentences equivalent to those currently available for heroin offenses. The Committee believes marihuana trafficking is a serious problem and one for which serious criminal sanctions should be imposed.

Program Oversight

The Committee's principal oversight activities with respect to the development of safety and nutritional standards for infant formulas were conducted by the Subcommittee on Oversight and Investigations. The Subcommittee conducted an extensive hearing, November 1, 1979, on issues raised by the marketing of a commercially prepared formula that was nutritionally deficient. The Subcommittee also examined the adequacy of existing Federal standards respecting the manufacturer of infant formula and the manner in which the Food and Drug Administration monitors the recall of formula products. A Subcommittee report, discussing the findings of their investigation and proposing specific legislation and administration recommendations, was issued as Committee Print 96–IFC 42, February 1980.

The Committee's principal oversight activities with respect to drug law enforcement were conducted by the Subcommittee on Health and the Environment in connection with its consideration of H.R. 6700, legislation to extend the authorization of appropriations for the Controlled Substances Act. A hearing on the legislation was conducted on March 7, 1980.

The Committee has not requested or received oversight findings with respect to either of these programs from the Committee on Government Operations.

Inflation Impact Statement

The Committee does not anticipate that the enactment of H.R. 6940 will have any adverse impact on the economy. To the contrary, the imposition of uniform formula nutritional and safety standards will reduce the likelihood of illness and costly hospitalization associated with inadequate infant nutrition.

The legislation does not authorize the appropriations of any additional funding. The Committee concurs with the comments of the Congressional Budget Office that "no significant additional costs to the government would be incurred as a result of enactment of this legislation."

Agency Reports

Agency reports on H.R. 6940 were not requested by this Committee. No reports were received at the time this report was filed.

Congressional Budget Office Cost Estimate

A cost estimate was requested and received from the Congressional Budget Office on H.R. 6940, when it was ordered reported by the Committee on Interstate and Foreign Commerce. A letter containing the cost estimate is included as follows.

67-331 O - 80 - 3

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., April 21, 1980.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed H.R. 6940, the Infant Formula Act of 1980, as ordered reported by the House Committee on Interstate and Foreign Commerce on April 17, 1980.

The bill would authorize the Department of Health and Human Services to establish regulations governing the manufacture and sale of infant formulas in order to assure that such formulas are safe and nutritious. In addition, the bill would increase penalties for possession of more than 1,000 pounds of marihuana and would amend the Psychotropic Substances Act to extend indefinitely existing federal controls on piperidine (those controls would expire January 1, 1981 otherwise).

Because such inspections and other activities necessary to enforce the provisions of this bill regarding infant formulas already take place today, those provisions would not result in significant additional costs to the federal government. Furthermore, according to the Drug Enforcement Administration, the costs of extending controls on piperidine would also be negligible. It is expected, therefore, that no significant additional costs to the government would be incurred as a result of enactment of this legislation.

Sincerely,

ALICE M. RIVLIN, *Director.*

SECTION-BY-SECTION ANALYSIS

FIRST SECTION

Short Title "The Infant Formula Act of 1980"

SECTION TWO

Adds new Section 412 to Chapter IV of the Federal Food, Drug and Cosmetic Act. Provides authority for the Secretary to establish nutritional, quality control, record keeping, notification and recall requirements necessary to insure that infant formula is safe and will promote healthy development.

Section 412(a)(1) establishes standards under which formula may be deemed to be adulterated. Formula is adulterated if it:

(1) does not contain required nutrients in accordance with the table set out in subsection (g) or as revised under paragraph (2).

(2) does not comply with necessary nutrient quality factors as prescribed under paragraph (2)(C).

(3) is not processed in accordance with appropriate quality control procedures or record retention requirements prescribed under paragraph (2)(D).

Section 412(a)(2) Formula nutrients, or the level for any nutrient required by subsection (g), may be revised by regulation. The Secretary is authorized to establish quality factors for nutrients and quality control procedures for formula processing.

Section 412(b) Formula manufacturers are required to notify the Secretary that their product is in compliance with subsection (a) in two instances.

(1) 90 days before the first processing of a new formula.

(2) Before first processing of an existing formula following a change in formulation or processing which the manufacturer determines may affect whether the formula is adulterated as determined under subsection (a)(1).

Section 412(c) Manufacturers of infant formula shall promptly notify the Secretary if they obtain knowledge which reasonably supports the conclusion that an infant formula may not be in compliance with the requirements of subsection (a)(1)(A) or may be otherwise adulterated or misbranded and as such presents a risk to human health.

The term "knowledge" is defined in (c)(2) to mean: (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

Section 412(d)(1) If a recall of an infant formula is begun by a manufacturer, the recall shall be carried out in accordance with the requirements prescribed by the Secretary under paragraph (2). The Secretary is required to review the actions taken by the manufacturer to implement the recall no less than every 15 days until the recall is terminated. The manufacturer is required to submit a status report to the Secretary on actions to implement the recall no less than every 14 days until the recall is terminated.

(2) The Secretary is authorized to prescribe the scope and extent of infant formula recalls.

Section 412(e)(1) Manufacturers of infant formula are required to keep and maintain records respecting formula distribution. Such records are limited to those necessary to the effective implementation and monitoring of formula recalls.

No manufacturer is required to maintain a record respecting the distribution of an infant formula longer than two years from the date the record was made.

(2) To the extent the Secretary determines that records are not being made or maintained in a manner to effectively implement and monitor recalls, the Secretary is authorized to issue regulations prescribing the form and manner in which such distribution records are to be made and retained.

Section 412(f) Special formulas represented and labeled for use by infants who have an inborn error of metabolism, low birth weight or which otherwise have an unusual medical or dietary problem are exempt from subsections (a), (b) and (c)(1). The Secretary may establish the terms and conditions for formulas represented and labeled for use by infants with special metabolic or dietary problems. The continuation of an exemption under paragraph (1) of this subsection is subject to compliance with applicable terms and conditions prescribed.

Section 412(g) Ingredients of formula intended for normal, full term infants are specified. The table of ingredients contained in the

bill reflects the 1976 recommendations of the American Academy of Pediatrics and may be revised by the Secretary pursuant to authority provided in Section 412(a)(2).

SECTION THREE

Amends section 201, of the Federal Food, Drug and Cosmetic Act, to define 'infant formula" as a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

SECTION FOUR

(1)-(3) Series of technical and conforming amendments.
(4) Adds new paragraph to section 704(a) of the Federal Food, Drug and Cosmetic Act. The paragraph permits the Secretary or his representative access to records, reports and test results necessary to confirm compliance with the requirements of section 412.

SECTION FIVE

Amends section 301 [Prohibited Acts] of the Federal Food, Drug and Cosmetic Act to make certain actions relating to Section 412 prohibited acts:

Subsection (a) Adds new paragraph to Section 301 providing:
(1) failure to provide the notice required by section 412(b) or 412(c).
(2) failure to make reports required by Section 412(d)(1)(B).
(3) failure to meet the recall requirements prescribed under section 412(d)(2).

Subsection (b)(4) Amends section 301(E) to include failure to maintain, permit access to, or copying of records required by section 412.

Subsection (c)(5) Amends Section 301(j) to prohibit the disclosure of trade secrets, obtained pursuant to Section 412, to any person other than to the Secretary, an officer or employee or the Department, or to the courts.

SECTION SIX

Section 412 of the Federal Food, Drug and Cosmetic Act (added by section 2) shall apply with respect to infant formulas introduced or delivered for introduction into interstate commerce on or after 90 days following the date of the enactment of this Act.

SECTION SEVEN

Requires the submission to the Congress of a report, prepared by the Secretary of Health and Human Services, on the long term health effects on infants of hypocloremic metabolic alkalosis.

SECTION EIGHT

(a) Amends Section 503 [Cooperative Arrangements] of the Controlled Substances Act to require the Attorney General to provide

annual descriptive and analytic reports to States on the distribution patterns of drugs and other substances subject to schedule II controls.

(b) Amends Section 203 of the Psychotropic Substances Act of 1978 to continue reporting requirements for the PCP precursor piperdine.

(c) Amends Section 401 [Prohibited Act A-Penalties] of the Controlled Substances Act to increase criminal penalties for the illegal distribution of a quantity of marihuana exceeding 1,000 lbs. Persons convicted of such a violation are subject to a term of imprisonment not to exceed 15 years and may be fined not more than $125,000. The maximum penalties are doubled in the case of individuals convicted of a prior drug-related felony.

Changes in Existing Law Made by the Bill, As Reported

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Federal Food, Drug, and Cosmetic Act

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CHAPTER II—DEFINITIONS

Sec. 201. For the purposes of this Act—

(a) (1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

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(z) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(aa) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

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CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

Sec. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

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(e) The refusal to permit access to or copying of any record as required by section *412 or* 703; or the failure to establish or maintain any record, or make any report, required under section *412*, 505 (i) or

(j), 507 (d) or (g), 512(j), (l) or (m), 515(f), or 519 or the refusal to permit access to or verification or copying of any such required record.

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(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 concerning any method or process which as a trade secret is entitled to protection.

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(s) The failure to provide the notice required by section 412(b) or 412(c) the failure to make the reports required by section 412(d)(1)(B), or the failure to meet the requirements prescribed under section 412(d)(2).

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CHAPTER IV—FOOD

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REQUIREMENTS FOR INFANT FORMULAS

SEC. 412. (a)(1) An infant formula shall be deemed to be adulterated if (A) it does not provide nutrients in accordance with the table as set out in subsection (g) or as revised under paragraph (2), (B) it does not meet the requirements prescribed under paragraph (2)(C), or (C) the processing of the formula is not in compliance with applicable requirements prescribed under paragraph (2)(D).

(2) The Secretary may by regulation—

(A) revise the list of nutrients in the table in subsection (g),

(B) revise the level for any nutrient listed in the table,

(C) establish requirements for quality factors for nutrients listed in the table, and

(D) establish such quality control procedures as the Secretary determines necessary to assure that an infant formula provides nutrients in accordance with subsection (a)(1)(A) and meets the requirements of subparagraph (C) and establish requirements respecting the retention of records of procedures required under this subparagraph.

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(b)(1) Not later than 90 days before the first processing of any infant formula for commercial or charitable distribution for human consumption, the manufacturer shall notify the Secretary whether (A) the formula provides nutrients in accordance with subsection (a)(1) and meets the applicable requirements prescribed under subsection (a)(2)(C), and (B) the processing of the formula will be carried out in accordance with the applicable requirements prescribed under subsection (a)(2)(D).

(2) Before the first processing of any infant formula for commercial or charitable distribution for human consumption—

(A) after a change in its formulation, or

(B) after a change in its processing,

which the manufacturer reasonably determines may affect whether the formula is adulterated as determined under subsection (a)(1), the manufacturer shall notify the Secretary of such changes and that the formula provides nutrients in accordance with subsection (a)(1) and meets the applicable requirements prescribed under subsection (a)(2)(C) and that the processing of the formula will be carried out in accordance with the applicable requirements prescribed under subsection (a)(2)(D).

(c)(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

(A) may not be in compliance with the requirements of subsection (a)(1)(A), or

(B)(i) may be otherwise adulterated or misbranded, and

(ii) if so adulterated or misbranded presents a risk to human health,

the manufacturer shall promptly notify the Secretary of such noncompliance or risk to health.

(2) For purposes of paragraph (1), the term "knowledge" as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(d)(1) If a recall of an infant formula is begun by a manufacturer, the recall shall be carried out in accordance with such requirements as the Secretary may prescribe under paragraph (2), and—

(A) the Secretary shall, not later than the 15th day, after the beginning of such recall and at least every 15 days thereafter until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2); and

(B) the manufacturer shall, not later than the 14th day after the beginning of such recall and at least every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risk to human health presented by the formula subject to the recall.

(e)(1) Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. No manufacturer shall be required under this subsection to retain any record respecting the distribution of an infant formula for a period of longer than 2 years from the date the record was made.

(2) To the extent that the Secretary determines that records are not being made or maintained in accordance with paragraph (1), the Secretary may by regulation prescribe the records required to be made under paragraph (1) and requirements respecting their retention under such paragraph. Such regulations shall take effect on such date as

the Secretary prescribes but not sooner than 180 days after the date of their promulgation, and they shall apply only with respect to distributions of infant formulas made after their effective date.

(f) (1) Any infant formula which is represented and labeled for use by an infant—

(A) which has an inborn error of metabolism or a low birth weight, or

(B) which otherwise has an unusual medical or dietary problem,

is exempt from the requirements of subsections (a) and (b). The manufacturer of an infant formula provided an exemption under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (c) only with respect to information described in paragraph (2) of such subsection.

(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a) and (b). The continuation of an exemption of an infant formula under paragraph (1) shall be subject to compliance with applicable terms and conditions prescribed under this paragraph.

(g) The table referred to in subsection (a) (1) (A) is as follows:

Nutrients

Nutrient	*Minimum* [1]	*Maximum* [1]
Protein (gm)	*1.8*	*4.5*
Fat:		
Gm	*3.3*	*6.0*
Percent cal	*30.0*	*54.0*
Essential fatty acids (linoleic):		
Percent cal	*3.0*	
Mg	*300.0*	
Vitamins:		
A (IU)	*250.0 (75 mg)* [2]	*740.0 (555 mg)* [2]
D (IU)	*40.0*	*100.0*
K (mg)	*4.0*	
E (IU)	*0.3 (with 0.7 IU/gm linoleic acid).*	
	5.0	
C (ascorbic acid) (mg)	*40.0*	
B_1 (riboflavin) (µg)	*60.0*	
B_2 (pyridoxine) (µg)	*35.0 (with 15 µg/gm of protein in formula).*	
B_6 (pyridoxine) (µg)	*0.15*	
B_{12} (µg)	*150.0*	
Niacin (µg)	*5.0*	
Folic acid (µg)	*50.0*	
Pantothenic acid (µg)	*1.5* [3]	
Biotin (µg)	*7.0* [3]	
Choline (mg)	*5.0* [3]	
Inositol (mg)		
Minerals.		
Calcium (mg)	*50.0* [3]	
Phosphorus (mg)	*25.0* [3]	
Magnesium (mg)	*6.0*	
Iron (mg)	*0.15*	
Iodine (µg)	*5.0*	
Zinc (mg)	*0.5*	
Copper (µg)	*60.0*	
Manganese (µg)	*5.0*	
Sodium (mg)	*20.0 (0 m Eq)* [4]	*60.0 (17 m Eq)* [4]
Potassium (mg)	*80.0 (14 m Eq)* [4]	*200.0 (34 m Eq)* [4]
Chloride (mg)	*55.0 (11 m Eq)* [4]	*150.0 (29 m Eq)* [4]

[1] *Stated per 100 kilocalorie.*

[2] *Retinol equivalents.*

[3] *Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.*

[4] *Milliequivalent or 670 milliliter of formula.*

[5] *Required to be included in this amount only in formulas which are not milk-based.*

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

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FACTORY INSPECTION

SEC. 704. (a) *(1)* For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized [(1)] *(A)* to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and [(2)] *(B)* to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence *or by paragraph (3)* shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j), section 507 (d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. *(2)* The provisions of the second sentence of [this subsection] *paragraph (1)* shall not apply to—

[(1)] *(A)* pharmacies which maintain establishment in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound,

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or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

[(2)] (*B*) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice;

[(3)] (*C*) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale;

[(4)] (*D*) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or

(B) required to be maintained under section 412.

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CONTROLLED SUBSTANCES ACT

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PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. (a) * * *

(b) Except as otherwise provided in section 405, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) * * *

(B) In the case of a controlled substance in schedule I or II which is not a narcotic drug or in the case of any controlled substance in schedule III, such person shall, except as provided in paragraphs (4) [and (5)], (*5*), *and* (*6*) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine of not more than $15,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine of not more than $30,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 4 years in addition to such term of imprisonment.

* * * * * * *

(6) In the case of a violation of subsection (a) involving a quantity of marihuana exceeding 1,000 pounds, such person shall be sentenced to a term of imprisonment of not more than fifteen years, and in addition, may be fined not more than $125,000. If any person commits such a violation after one or more prior convictions of him for an offense punishable under paragraph (1) of this paragraph, or for a felony under any other provision of this title, title III, or other law of the United States relating to narcotic drugs, marihuana, or depressent or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than thirty years, and in addition, may be fined not more than $250,000.

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PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

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COOPERATIVE ARRANGEMENTS

SEC. 503. (a) * * *

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(c) The Attorney General shall annually (1) select the controlled substance (or controlled substances) contained in schedule II which the Attorney General, in his discretion, determines to have the highest rate of abuse, and (2) prepare and make available to regulatory, licensing, and law enforcement agencies of States descriptive and analytic reports on the actual distribution patterns in such States of each such controlled substance.

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SECTION 203 OF THE PSYCHOTROPIC SUBSTANCES ACT OF 1978

TITLE II—PCP CRIMINAL PENALTIES AND PIPERIDINE REPORTING

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SEC. 203. (a)(1) * * *

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[(d) On January 1, 1981, section 310, subsection (d) of section 401, paragraph (9) of section 402(a), subparagraph (C) of section 402(c)(2), and clause (B) of section 403(a)(4) of the Controlled Substances Act (as added by this title) are repealed.]

Senator METZENBAUM. In our examination of the legislation today, we will review the events that led to the discovery of the chloride deficiencies and what has happened to those babies who are known to have been fed the deficient formula.

In addition, we will hear testimony from two Members of Congress regarding the House bill and comments on the proposed legislation from the FDA, consumer parents, the Infant Formula Council, and the American Academy of Pediatrics. We will also hear testimony from the Center for Disease Control regarding their identification and followup efforts on affected children.

Senator Schweiker?

OPENING STATEMENT OF SENATOR SCHWEIKER

Senator SCHWEIKER. Thank you, Mr. Chairman.

Nothing is more critical to the health and early development of our children than proper infant nutrition. For millions of American babies, this means that the formula they receive as the sole or primary source of nutrition must contain adequate levels of all essential nutrients.

Confidence in the safety of infant formula was shaken last summer when we discovered that two widely used products had been reformulated and marketed without adequate testing. The products were seriously deficient in chloride.

Lack of chloride can severely impair normal growth and development, causing a condition known as metabolic alkalosis. The infants fail to gain weight and develop normally. More than 130 cases of babies suffering from this condition have been reported to the Center for Disease Control.

Product recalls were initiated, but subsequent congressional investigations and news reports raised serious questions about the thoroughness and effectiveness of public information and recall procedures. In addition, the Food and Drug Administration's standards for infant formula, in effect at the time this problem was discovered, were inadequate and out of date, in light of current knowledge of what is needed for good health. FDA standards did not insure the safety of the most important food many children will ever eat.

I know my colleagues on the subcommittee share my concern about these unfortunate events. Although FDA reported that most children appeared to improve dramatically once use of the deficient formula was discontinued, parents are understandably worried about lingering effects. Continued monitoring is critical.

Parents should be able to rely with confidence on the formula they feed their babies. The manufacturers of infant formula bear a heavy responsibility to insure the safety of these unique food products. FDA, as the primary Federal agency charged with protecting Americans from unsafe foods, must act effectively to prevent these kinds of hazards, which jeopardize human health.

The House of Representatives last month passed legislation aimed at preventing any recurrence of problems related to inadequate testing of infant formula which endanger infant health.

Our witnesses today include Congressmen active in that effort, concerned parents, responsible Government officials, infant nutrition experts, and representatives of private industry. We will hear

their views on how we can best insure the safety of the infant formula products that are so vital to our children's health.

Senator METZENBAUM. Thank you very much, Senator Schweiker. Your help on this matter has been invaluable.

Senator Hatch, do you have an opening statement?

OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. Thank you, Mr. Chairman.

Today's hearing and the results of it are a real test for our subcommittee, as well as the Senate as a whole. It will test our commitment to protecting both the citizen as consumer and the integrity of the marketplace.

We are about to receive testimony from a number of witnesses which will outline a series of occurrences which may have caused injury to a number of infants. The recall last year of two products from manufacturers of infant formula occurred because of a deficiency in those products of essential ingredients. It is imperative that such occurrences do not happen again.

A test which this subcommittee must face is whether we can respond to that occurrence without destroying availability of a product which has contributed significantly to the improvement of infant nutrition in this country since World War II. After all the testimony is received and after we have had an opportunity to review the conclusions of the witnesses, I believe we will find that there is a need for Congress to set new statutory authority for FDA.

The form of any legislative action we take must insure that infant formula, which is the sole source of nutrition for infants in their first months of life, contain essential ingredients at appropriate levels. The legislation should provide the manufacturers of infant formulas to conduct the necessary testing at appropriate times to insure the integrity of their product.

Finally, legislation should serve to reassure the public that infant formula is safe for their newborn children and meets Government standards of nutritional effectiveness.

I also believe, Mr. Chairman, that there are some things that this legislation should not do.

First, it should not create a series of regulations which are neither enforceable nor effective;

Second, it should not in any way work as an impediment to the improvement of the product through ongoing developments in scientific and nutritional research.

Finally, Mr. Chairman, I do not believe the legislation should contain any provisions which restrict the supply of infant formula to the public. The House has already acted on a bill which has been endorsed by the Infant Formula Council. We would be well served to examine this bill in detail, and to decide if this type of needed balance has been achieved.

As you will hear later this morning, infant formula has a unique place in American history. Manufacturers of it have an extremely good record over the decades of use. The seriousness of the incident which led to this hearing should not be minimized. However, I hope we act in a responsible manner and meet the test of continuing the availability of these products in the safest possible manner.

Thank you, Mr. Chairman.

Senator METZENBAUM. Thank you very much, Senator Hatch. Congressman Gore, happy to have you here with us today.

STATEMENT OF HON. ALBERT GORE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. GORE. Thank you very much, Mr. Chairman, members of the committee.

I appreciate the committee's invitation to appear here today. I was pleased to learn that you, Mr. Chairman, have a strong personal interest in this issue, and I am grateful for the support by Senator Schweiker and Senator Hatch, and that the committee has been carefully evaluating the standards for the single most important food that the majority of American infants consume—manufactured infant formulas.

I have found a general consensus among interested parties regarding the need to assure American parents that infant formulas, which are often the sole source of nourishment for newborn children, are safe and healthy.

Our understanding of the components of mother's milk and their interrelationships is extremely limited, so our knowledge of what constitutes an optimal synthetic formula is also limited. At a minimum, in my judgment, it is not unreasonable to require the manufacturers of infant formula to take all necessary steps to prove that their products are of acceptable quality.

The infant formula manufacturer's endorsement of H.R. 6940, the Infant Formula Act of 1980, which was approved by the House 388–15, signals the broad support for infant formula health and safety standards. The modest requirements of the legislation have been well received by the industry.

I would like to express my thanks to the industry for not just taking a mossback position and digging in their heels and saying, no, to any additional legislation. They have been cooperating in helping us address this problem. It is laudable, and I sincerely believe that the House and Senate will fashion reasonable and effective legislation. I thought it might be useful this morning for me to quickly describe the events that led to our investigation into this issue in the House.

Last fall, my colleague, Ron Mottl, and I requested the Commerce Oversight and Investigations Subcommittee to investigate the sequence of events leading to the marketing of two of the adulterated formulas. Dr. Shaneroy, of Memphis, Tenn., first put two and two together and discovered what was causing the problem that so many infants around the United States were experiencing. When we looked into it, we learned that these two formulas, Neo-Mull-Soy and Cho-Free had been marketed for 15 months, beginning in March 1978, by the Syntex Corp.

Syntex had reformulated the two products and then mass marketed them without testing the new compositions in order to make sure they contained sufficient amounts of all the nutrients needed for healthy development of infants. We also found that formula manufacturers are not required by law to conduct such tests, nor are they prohibited from marketing a formula deficient in vital nutrients.

In this case, the consequences were tragic. The level of chloride, a vital nutrient for newborn children, had been drastically lowered during the reformulation of Neo-Mull-Soy and Cho-Free. As a result, a number of children suffered from a life-threatening chemical abnormality called metabolic alkalosis, which impedes normal development. The long-term effects of this disease are as yet unknown.

Unfortunately, this disturbing tale gets even worse. A recall was finally announced 15 months after the reformulated product was first made available to the public, but neither the Food and Drug Administration, FDA, or Syntex, appreciated the gravity of the situation or worked to assure a speedy withdrawal of the deficient formulas. Neo-Mull-Soy and Cho-Free were actually found on store shelves across the country on the day of the subcommittee's hearing, 3 months after the recall was initiated. The Oversight Subcommittee also learned that there are no easily enforceable regulations for the recall of deficient formulas.

After completing its investigation, the subcommittee identified three clear needs regarding infant formula:

First, infant formula manufacturers should be required to include all essential nutrients in any infant formula;

Second, formula manufacturers should be required to test to make sure their products include sufficient amounts of all vital nutrients before marketing them;

Third, FDA recall procedures must be improved to assure that adulterated products are quickly withdrawn from the marketplace.

The legislation reported by the House would accomplish these objectives. I was pleased to learn that your bill, Mr. Chairman, generally would achieve the same result. I commend you and your interest and actions in this area.

I note that the Senate bill, S. 2490, does not contain a specific list of nutrients that would be included in any infant formula for normal babies. I urge the committee to include in the legislation the nutrient list coupled with a provision allowing FDA to modify the list by regulation based on new scientific information.

The scientific community, FDA, and the infant formula manufacturers already subscribe to this list. The inclusion of the nutrient table will insure that a specific standard is immediately enforceable. Otherwise, the promulgation of regulations in this area would allow months and possibly years to pass before an acceptable standard is codified.

Mr. Chairman, this point is one that we spent a good deal of time on over on the House side, and there was initially some objection to putting a specific list in the bill. But FDA endorses the approach that we took. The manufacturers have now endorsed that approach. The scientific community endorses that approach, and there is a simple reason why it is better to go that way than to simply give the FDA the authority to come up with such a list.

We know what the results of all the scientific study in this area are. There is a consensus on what the list should be, right now, based on current scientific knowledge.

If, on the other hand, we tell the FDA to do it, they have to, by law, follow certain procedures, Administrative Procedures Act, and it is a long drawn out process, and it could, our best estimates are

that it could take as long as a year and possibly longer in order to get through that long, complicated process. That is the reason FDA endorsed our approach of putting it in the statute and then giving FDA the statutory flexibility to make any changes in that list, so that if changes are needed, it simply shifts the burden of delay and it shifts the burden in a way that it gives more protection quicker to the infants in this country.

I would also like to comment briefly on the detention authority in the Senate bill, S. 2490. I believe this is a valuable step but it does not go far enough. The Syntex incident revealed the dangers created when a hazardous product is in the marketplace and a cumbersome recall effort is set in motion. A detention action would prevent further distribution of the product but it would not improve our existing mechanism to recall dangerous formulas from store shelves. I think we have learned a great deal from the haphazard Syntex recall. It illustrates FDA's inability to insure the quick removal of dangerous products.

Although FDA and Syntex shared responsibility for the recall, both failed to follow up the initial recall warnings or to monitor the progress of the removal effort.

FDA's enforcement policy regulations state that:

> FDA will monitor a firm's recall to assure that it is promptly and effectively conducted. If the recall is deficient, the agency will initiate appropriate regulatory action.

FDA, during the Syntex recall, failed on both accounts. The agency did not know a problem existed because it did not make the effort to look. FDA did not monitor the recall. Consequently, the agency could not initiate appropriate regulatory action. In fact, the agency assigned a low priority to the life-threatening hazards posed by the deficient formulas until its misguided policy was reviewed in a public hearing before the Oversight Subcommittee.

FDA was understandably embarrassed and concerned about its performance during the recall. The subcommittee concluded that the FDA's procedures with respect to the recall approached a total disregard for the health and safety of the affected infants. This inept and negligent exercise by the FDA was a classic bureaucratic nightmare.

In the wake of those hearings, the agency has sent out confusing signals several times regarding its position on the recall provision. Today, the agency apparently favors language which would clarify FDA's ability to obtain an affirmative injunction from the courts to recall adulterated or misbranded infant formulas.

FDA's proposal would complement the recall provision in the House bill. I encourage the committee to look favorably upon both provisions. They would be a substantial improvement over existing law.

Senator METZENBAUM. We expect to move with FDA to put together statutory language to implement the recall procedure, because I think that is a very critical aspect of the whole subject.

Mr. GORE. That is very encouraging news, Mr. Chairman.

I will conclude my statement briefly by thanking you and the members of the subcommittee again for your efforts in this area and hope that our common efforts to assure American parents that infant formulas are safe and effective will come to fruition.

Thank you very much.

Senator METZENBAUM. Thank you very much, Congressman Gore. I will have some questions for you after we have heard from Congressman Mottl. I think that is the first Congressman from my own community to be testifying before a committee which I have the opportunity to chair. I am happy to have you with us this morning.

STATEMENT OF HON. RONALD M. MOTTL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. MOTTL. Thank you very much, Senator Metzenbaum. It is certainly a pleasure to be in front of your subcommittee.

I want to thank you and Senator Schweiker for giving me this opportunity to address the subcommittee with my views on the Infant Formula Act of 1980.

As my colleague, Al Gore, pointed out in his statement, our Oversight and Investigations Subcommittee found that two infant formulas were marketed even though they lacked an important and vital salt derivative. The result was that more than 130 infants became seriously ill. Once the deficient formulas were discovered, the Food and Drug Administration relied on a voluntary recall to get the formulas off the shelves. A spot check by the FDA nearly 3 months after the voluntary recall began, showed some of the dangerous formula was still being sold.

With swift action by Chairman Waxman's Subcommittee on Health, hearings were held and a consensus on a bill was reached for the protection of our infants.

I am pleased to note that the House passed H.R. 6940, the Infant Formula Act of 1980, by a 388 to 15 margin. Clearly, this is an indication of the soundness of this proposal. I might add parenthetically that I think those 15 negative votes were due—and I think Al would concur—with regard to the marijuana provisions that were attached thereon. Otherwise, this probably would have no negative votes in the House of Representatives.

H.R. 6940 would extend protection to one of our Nation's most precious natural resources, our infants, who are totally dependent on us for their safety and well-being.

During the investigation into deficient infant formula, we learned that there were no quality control or testing requirements for infant formulas and no guidelines for the recall of deficient formulas. Also, there were no Federal statutes or regulations which require that infant formula contain all nutrients recognized as essential. The bill would correct these shortcomings by requiring:

That infant formula being marketed as the sole source of nutrition for normal infants include minimum amounts of all essential nutrients;

That formula be tested to insure nutritional adequacy before they are mass marketed;

That the Food and Drug Administration establish mandatory procedures for the recall of infant formula.

Another important aspect of the legislation is a provision for an ongoing study to determine the long-range effects on any infant made ill by deficient formulas.

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H.R. 6940 will insure thousands of parents that the infant formula they feed their children will be safe and nutritious. There currently are no such guarantees.

It would appear to me that the differences between S. 2490 and H.R. 6940 can be worked out in a satisfactory way for all. I also hope that any disagreements do not affect the overall intent of the legislation, to provide our babies with wholesome and nutritious formula.

I might add, Mr. Chairman, that in the Senate bill, I would certainly commend you and your cosponsors that you do place some emphasis on the product such as how to use endorsements of breast feeding, which we all know is the most nutritious product for our babies of America, and the summary of health benefits and risks. I think that is commendable, and I would like to see that stay in the legislation. Possibly in Conference, that could be incorporated in both pieces of legislation.

I would also like to have submitted into the record an excerpt from an article that appeared in the Cleveland Press yesterday that states:

TWO SUE BABY FOOD MAKER

Parents charge child's brain damaged and ask $25 million, $10 million for compensatory damages and $15 million for punitive damages.

I would like to have that inserted in the record.

Senator METZENBAUM. Without objection, it will be included in the record.

Mr. MOTTL. Thank you very much.

I want to commend you for your efforts in having this hearing and your sponsorship of needed legislation in the Senate here.

Senator METZENBAUM. Thank you very much, Congressman Mottl.

Congressmen, your legislation and our legislation represents somewhat different approaches to try and solve the same problem, but they both move in the same direction. They both have the same objective.

Not wishing to address myself to the specifics of the House bill or the Senate bill, I would like to ask you a couple of questions regarding the premises of your proposal.

First, from your investigation, is it clear that minimum nutrient requirements should and must be established for infant formula?

Mr. GORE. That is absolutely clear. We ought to be able to give the American parents assurances that all infant formulas contain at least a minimum amount of the necessary ingredients. Since World War II, the popularity of synthetic formulas has really grown tremendously. For thousands and thousands and thousands of years prior to that time, a mother's breast milk was the sole source of nourishment for infants. As we moved quickly into this new source of nourishment for infants, and given the problems which have occurred, it is only prudent for us to give those assurances to parents in the kind of mass marketing society that we have.

Senator METZENBAUM. Is there any question in your mind that FDA should have the authority to inspect manufacturing records of processors and authority to establish standards of quality control?

Mr. GORE. There is no question in my mind that that should be done. It is the most efficient way to accomplish the results we want to accomplish without causing the kind of regulatory bureaucratic problems that Senator Hatch was concerned about in his opening statement. This gets it done in the most efficient way.

Senator METZENBAUM. Congressman Mottl?

Mr. MOTTL. Yes.

If I may, Mr. Chairman, with regard to your first question, I think I would concur with my learned colleague from Tennessee that it is absolutely essential that this be included in the legislation with regard to a minimum amount of nutrients. I think in mother's milk there are some 400 nutrients. I do not see how we can ever compete with that. That is why I think most pediatricians claim that mother's milk is by far the best. We should have at least some minimum established criteria as to minimum amount of nutrients in these products. I think it is the Academy of Pediatrics that has prescribed the minimum amount that is necessary.

With regard to your second question, I again would concur with my colleague that we should be able to go and see that they have quality control with regards to various drug companies that would produce these various products for consumption by consumers of America.

Senator METZENBAUM. Senator Schweiker, any questions?

Senator SCHWEIKER. Thank you, Mr. Chairman.

First, again, I want to commend Congressman Gore and Congressman Mottl for their leadership in this area.

I would like to pursue for a moment the nutrient list issue. I would direct my questions to either of the Congressmen. Is there a fairly strong consensus in the scientific community that the nutrients and nutrient levels in the list you have incorporated into your bill are the basic nutrients, or is there some controversy about the appropriateness of any of them?

Mr. GORE. This list has been out for review by the scientific community for several years. There is no objection or disagreement that I know of to the components of the list. Our knowledge of what constitutes an optimal formula is very limited.

My colleague, Mr. Mottl, mentioned the 400 known and identified substances in mother's breast milk. Of those 400, there are, I think, a couple dozen in the best of the formulas on the market. So while this list is the best we now know of, our knowledge is limited in this area. But there is no disagreement about the components on that list.

Senator SCHWEIKER. I see on your list, too, that you have established maximum amounts for vitamins which can be toxic, such as vitamins A and D. In other areas, where there is no toxicity problem, there appears to be no maximum; you are only prescribing a minimum level. Is that correct?

Mr. GORE. Correct.

Senator SCHWEIKER. Knowing how long and difficult it is to get a regulation through, I think I can concur with the point you are making about putting the nutrient table in the bill, as long as there seems to be general agreement, on the contents of the list, which apparently there is in this case. We save an awful lot of time and controversy by starting on this basis. I do think it makes sense

to put a minimum list in the legislation itself, assuming that nobody is taking serious issue with elements on the list on scientific grounds, and then allow the Secretary to promulgate changes through new regulations as our knowledge improves. We avoid the initial regulatory delays and get something in place as soon as we can.

Mr. GORE. There may be some residual arguments against doing this. Understand that this is a point of controversy. It is just a question of where you want to put the burden of delay. Either way, the FDA has authority, by regulation, to make changes in the list, in our approach, or to come up with an entire list in the alternative approach. I think the burden should be shifted to a point where it will not fall on infants consuming formula, that they will have the benefit of protection while delay is going on.

Senator SCHWEIKER. Thank you.

Senator METZENBAUM. I think your point is a good one. Once there are minimum nutrient requirements in the bill, there is at least a starting point. From that point, changes can be made.

I want to thank you both for your testimony and your support.

I would like to make just a general observation. We are discussing today a situation where private industry, permitted on its own to act or refrain from acting, has really failed to meet their responsibility. Many people in this country often speak out about Government overregulation. I too am concerned about Government overregulation. But absent legislation of this kind, I fear that problems would continue in the infant formula industry.

I think this is an important instance where the Government must step in to fill a vacuum because, absent their doing so, many of our infants might continue to be exposed to dangerous infant formula. I think you would agree with me that there is a need in this instance for the Government to intervene. Industry has failed to do so.

I thank you very much for your support and help.

Mr. GORE. Thank you, Mr. Chairman.

Senator METZENBAUM. We now have a panel of witnesses: Stephen and Barbara Gasper, from my own State, from Hamilton, Ohio.

Mr. and Mrs. Gasper, would you come to the table, please? Happy to have you with us this morning.

Mark and Janet Marcantonio from Rhode Island. Would you please come to the table. I would like to say to them I know that Senator Pell had hoped to be with us this morning but by reason of illness in his own family he could not be here. He wanted me to express his regrets.

Larry and Lynne Pilot, from Arlington, Va. Happy to have you with us this morning. Would you come to the table, please.

Senator SCHWEIKER. It looks like we are in a pediatric ward this morning.

Senator METZENBAUM. I have participated in many hearings, but I do not know of any better supporting cast than we have this morning. The young babies that we have with us this morning add special flavor to the hearing.

Mr. and Mrs. Gasper, we are happy to have you here today. Please proceed.

STATEMENTS OF STEVEN AND BARBARA GASPER, HAMILTON, OHIO; MARK AND JANET MARCANTONIO, R.I.; AND LARRY AND LYNNE PILOT, ARLINGTON, VA.

Mrs. GASPER. Our daughter, Sarah, was born March 13, 1979. Her first formula was Similac with iron.

After several weeks, she became colicky, so our pediatrician recommended we change to regular Similac. Ten days later, she was still having problems digesting the formula and our pediatrician decided to change to a soy-based formula. He indicated Neo-Mull-Soy, saying that babies seemed to like the taste better than other soy-based formulas.

Within a week, Sarah had become so constipated, I called his office for advice. I was told to mix a teaspoonful to a tablespoonful of Karo syrup in her bottles, depending upon need. I found she required a tablespoonful of Karo in every bottle and she still was constipated. After another call to the pediatrician, I was told to use infant suppositories. She continued to have this problem severely the entire time we were using Neo-Mull-Soy.

Sarah gained weight rapidly, which could only be expected with six tablespoonfuls of Karo syrup every day in a 2-month-old baby. At times, Sarah would spit up what would seem like an entire feeding, but she did continue to do well. Sarah had begun to have cereal in addition to formula at about 2 months, but I used a brand which is salt-free and I mixed it with the Neo-Mull-Soy.

By 3 months, our pediatrician was asking if she was turning over in her crib; she was not making any effort.

At 5 months, and at my request, our pediatrician felt she could handle Advance, which is a formula closer to cow's milk. Neo-Mull-Soy was expensive and difficult to find.

When I took her for regular checkups, I was asked about physical developments—turning over, sitting up, and crawling. Each time, I had to say she was not accomplishing these things. Sarah was 6 months old before she rolled over—much past the normal age.

At 7 months, the pediatrician discussed a developmental test known as a Denver test. The reason he recommended this, to quote his records, Sarah had "delayed gross motor development." At different stages this test was brought up by several different doctors in the practice, but all seemed reluctant to actually schedule it. She still has not been tested. It was repeatedly suggested that we wait.

At 10 months, she started sitting up fairly well. If I put her in a sitting position, but it was another month before she sat up on her own. She was crawling at 11 months, but it was not the normal crawl. Her desire to move around was strong enough that she pulled herself with one elbow and pushed with one knee. She finally crawled on hands and knees at 13 months—slightly past the age when most children start walking.

Sarah is now 15 months old and still crawling. She has recently started pulling herself up on to furniture, but is not attempting to walk and is, at least, several months away from that point.

As far as the prognosis for her future health and development, after being off Neo-Mull-Soy formula for 9 months, she has not

gained any lost ground. Physically she is as far behind or further than ever.

Given the length of time it has taken her to acquire the very basic skills, I question that she will ever be able to excell in anything physical. I cannot say that she will be coordinated or quick enough to learn to ride a bicycle or any other physical achievement.

I would give anything if I could say with certainty that she will develop normally, that she will be physically strong and able. I will never know if she has reached her full potential, or if what I gave her, trusting in good faith, as a baby, has robbed her of a gift she might have had.

And on the other side of the issue, there may be no irreparable damage, but that is something we cannot know for certain, either now or later.

There are several doctors in pediatric clinics we used when we expressed concern on Neo-Mull-Soy, and they did not call me about it; I read it in the newspaper, and I was told there was nothing to worry about. When I contacted them regarding this situation, they would not discuss the situation with me at all. Because I have been and am concerned about my child's condition, I have been termed overanxious by at least one of these doctors. I did not expect Sarah's problems to stem from the use of Neo-Mull-Soy until I read an article about the Formula Committee here in Washington. I was aware she had a problem, but I never dreamed it could be caused by the formula.

I do not blame my doctors, but I am concerned that they made no effort to test Sarah.

Our children are our most valuable asset. We have to do everything in our power to see that they develop strong and capable. To allow this type of thing to happen is a gamble we cannot afford to take.

I feel there should be greater effort to locate and identify these children and children who have been affected should receive both immediate and long-range testing to ascertain if there is an existing problem, or if they should develop any problems that could be related to the Neo-Mull-Soy formula.

I believe that this should be a secondary part of any infant formula act, if that is what is necessary to insure that a program such as this is set up.

We, as citizens, expect more than has been delivered from our government and private companies that serve us. Up until now, I blindly accepted the idea that the goods I brought were safe and tested, especially where an infant was concerned. I would not have believed this kind of carelessness and neglect could exist in processing foods for a baby's consumption.

Please, for the sake of our children to come, make every effort to be certain this cannot happen again. Pass this legislation setting controls and guidelines requiring the pretesting of infant formulas.

How would you feel if this had happened to your child?

Senator METZENBAUM. Thank you very much, Mrs. Gasper. I would not feel very good about it.

How did you happen to start Sarah on Neo-Mull-Soy? Was that recommended by the doctor?

Mrs. GASPER. Yes, by name.

Senator METZENBAUM. By name?

Mrs. GASPER. Yes.

Senator METZENBAUM. After the problem developed, then he recommended that you feed the child Karo syrup?

Mrs. GASPER. Right, for the constipation. A tablespoon in every bottle.

Senator METZENBAUM. Did you ever discuss with the doctor that maybe Neo-Mull-Soy was the problem itself?

Mrs. GASPER. I did not even suspect it. I would not have believed it could have been caused by the formula. I have another child 4½, and he did not have this problem. He was also on a soy-based formula.

Senator METZENBAUM. But you told the doctor that the only food you were feeding the baby was Neo-Mull-Soy?

Mrs. GASPER. Yes. They did not suggest that you use anything else until 6 months. I did because she acted like she was still hungry.

Senator METZENBAUM. The doctor never raised the question that the formula might be the problem?

Mrs. GASPER. No. And he still has not.

Senator METZENBAUM. The only way you learned that Neo-Mull-Soy was the problem was by reading about it in the newspaper?

Mrs. GASPER. That is right.

Senator METZENBAUM. That was in the Cincinnati Enquirer that you read the story?

Mrs. GASPER. I read the Knight News Service recall, and I asked him and he said, do not worry about it. Then I read the story about the Formula Committee, and that is when I contacted someone.

Senator METZENBAUM. You contacted a parent group here in Washington after that?

Mrs. GASPER. That is right.

Senator METZENBAUM. Has anybody given you any idea of prognosis for the future?

Mrs. GASPER. No; they have not. We are looking into testing her now.

Senator METZENBAUM. Many people think the Government ought to stay out of private industry regulation.

How do you feel about it?

Mrs. GASPER. I am not for more Government regulations than are needed. But if this type of thing can happen, then obviously there should be a law.

Senator METZENBAUM. You think there needs to be a law in this instance?

Mrs. GASPER. Very definitely.

Senator METZENBAUM. Senator Schweiker?

Senator SCHWEIKER. Thank you, Mr. Chairman.

Mrs. Gasper, how old was your daughter when you took her off Neo-Mull-Soy?

Mrs. GASPER. Five months.

Senator SCHWEIKER. Did you notice a change of any kind when you switched formula?

Mrs. GASPER. Well, constipation quit immediately. She would spit up almost the entire bottle at times, and that quit immediately also. But I still really did not think it was a problem.

Senator SCHWEIKER. You would have no reason to think it was. What formula did you put her on when you took her off the Neo-Mull-Soy?

Mrs. GASPER. Advance. It is a cross between regular formulas and it is for older children, toddler-type children. Closer to a cow's milk formula.

Senator SCHWEIKER. So, your daughter was on chloride deficient formula for how long?

Mrs. GASPER. For approximately 4 months.

Senator SCHWEIKER. I gather from your testimony you have seen the constipation and some other symptoms improve when you changed formula, but as far as your daughter's future progress and development are concerned, you are still very uncertain——

Mrs. GASPER. Definitely I cannot see where she had gained any ground. Physically, she is very, very slow.

Senator SCHWEIKER. At this point, is there any expert in this disease or this deficiency that can give you straight advice or tell you what to expect, or are we operating strictly in unknown territory?

Mrs. GASPER. I do not know. I have not found anyone.

Senator SCHWEIKER. You have not found anyone who can give you——

Mrs. GASPER. I am looking into that now.

Senator SCHWEIKER. Thank you.

Senator METZENBAUM. Mrs. Marcantonio, we are very happy to have you here. You can either read your statement or if you are more comfortable in just talking, that is fine, too.

Mrs. MARCANTONIO. Brian was born on July 7, 1978. He was the second of our two children. For the first 3 months, I breastfed Brian. He started to spit up 2 weeks after we came home from the hospital; and after about 3 months, it was really getting to me that he was allergic to my milk. I talked to our pediatrician about it, and he suggested alternating between Neo-Mull-Soy and breast feeding. I alternated for 1 week, and at that time I thought I saw some improvement in the spitting up.

But at the same time, he had to be kept in an upright position for 1 month, and he had to sleep in an infant seat at all times. It really was the gravity that held the formula down, because after 1 month he started spitting up again. At this time, he was still on Neo-Mull-Soy. An X-ray and GI series was done, and both were negative.

He was seen by a pediatric neurologist in December to rule out any abnormality of the brain that may have been causing the spitting up. We met with our pediatrician in the latter part of January where we discussed Brian, and he said "Something happened to this baby between 3 and 4 months" and he didn't know what it was. He said he wasn't satisfied with his progress. He told us he wanted to put him through a series of tests for failure to thrive.

On February 1, 1979, Brian had a sweat test, urinalysis, EKG, CBC, amino acids—all negative.

On February 10, Brian had repeated blood work and still continued with severe congestion—he was seen by his pediatrician who then ordered a repeat sweat test. This was also negative.

The T3T4T7, TSH, BUN, creatinine were done—all normal. He also had bone age studies done in February which were normal. He had his 1 year checkup in July, and at this time, we knew his development was behind but our pediatrician wanted to wait a couple more months before having him seen by a pediatric neurologist in Boston.

Brian was taken off Neo-Mull-Soy the middle of August, when we could not find it any longer and heard it had been recalled. He was put on another soy-bean formula called Soyalac.

At the end of August, we were very concerned and upset by Brian's lack of progress and requested an appointment be made as early as possible with the pediatric neurologist at Massachusetts General Hospital. The appointment was made for September 27, 1979.

Brian's development improved within that month, his first month off Neo-Mull-Soy. He was examined by Dr. Robert Delong. He called Brian's problem a pseudo retardation which is children lacking proper nourishment due to excessive spitting up.

Due to his delayed development, we enrolled Brian at Meeting Street School. He was evaluated by three therapists, occupational, physical, and speech. He was also given the Denver developmental test. His age at that time was 18 months, however, his fine motor control was at a 10 or 12 month level. His gross motor was back at 7 to 9 months. His perception and understanding were at a 12 to 14 month level, and there was no speech, which is abnormal after 15 months of age.

He was also examined by the pediatrician at the school, and an EEG, brain wage, was recommended.

On January 21, 1980, Brian was examined by Dr. Taranth Shetty, a pediatric neurologist. The brain was normal. Dr. Shetty was concerned, though, with his slow development and said he would like to investigate further. He then ordered a CAT scan.

The CAT scan showed an abnormality in the frontal area of the brain, cause unknown, which accounts for his slow development.

Brian now is attending the Arthur Trudeau Center, a school for retarded and developmentally disabled children. Therapists work with Brian for a 3-hour session on Mondays, Wednesdays, and Thursdays. Brian and I still attend Meeting Street School once a month so we as a family can learn how to help him at home.

He can now crawl, pull himself to a standing position, only in the crib; and we have heard a couple of words. We can only hope for the future.

Considering all of the reported infant problems, all of a single nature, it is our firm belief that Neo-Mull-Soy is solely responsible for Brian's lack of development thus far, and God only knows what the future brings.

If you analyze the reported illnesses nationally, the one common denominator is Neo-Mull-Soy. Since the FDA has scientifically proven it lacked chloride, a vital nutrient, something must be done to prevent this tragic situation from ever happening to anyone else.

This incident has caused us and our family much heartache and mental anguish. There is no margin for error in the manufacturing of infant formulas.

I still cannot believe this all happened. It is like a nightmare to us.

Senator METZENBAUM. Mr. Marcantonio, did you want to say something?

Mr. MARCANTONIO. If God is with us, OK, maybe we are going to make out all right.

[The joint prepared statement of Mr. and Mrs. Marcantonio follows:]

Statement of Janet and Mark Marcantonio

Subcommittee on Health and Scientific Research

Hearing on S.2490

The Infant Formula Act of 1980

June 12, 1980

On July 7, 1978, I gave birth to a healthy 7 lb. 4 oz. baby boy. For the first three months Brian was breastfed and appeared to be progressing normally. At three months of age his weight was 12 lbs. 8 ozs.

During this period of time he spit up daily, occasionally projectile vomiting, which made me question if he was allergic to my milk.

An X-ray (GI Series) was done to rule out pyloric stenosis. X-ray results were negative. At the end of October with the advice of my pediatrician, Brian was started on Neo-Mull Soy, alternating with breastfeeding. This regiment was carried out for one week. At the end of the week the breastfeeding was stopped, leaving his only source of nutrition to be Neo-Mull Soy. Within one month the following symptoms occurred: some weight loss, lethargy, severe congestion, which lasted until the end of February. Two chest X-rays were done to rule out Bronchitis and or Pneumonia - both negative.

He was seen by a pediatric neurologist in December to rule out any abnormality of the brain that may have been causing the spitting up. We met with our pediatrician in the later part of January where we discussed Brian, and he said "Something happened to this baby between three and four months and he didn't know what it was". He said he wasn't satisfied with his progress. He told us he wanted to put him through a series of tests for failure to thrive. On February 1, 1979 Brian had a Sweat Test, urinalysis, EKG, CBC, amino acids - all negative. On February 10, Brian had repeated blood work and still continued with severe congestion - he was seen by his pediatrician who then ordered a repeat Sweat Test. This was also negative. The T_3 T_4 & T_7 had to be repeated because of a discrepancy. At this time Brian was referred to a Pediatric Endocrine Clinic where a GI, Sm. Bowel, Barium Swallow, T_3 T_4 T_7, TSH, BUN, creatinine were done - all normal. He also had bone age studies done in February which were normal. He had his one year check-up in July , and at this time we knew his development was behind but our pediatrician wanted to wait a couple more months before having him seen by a Pediatric Neurologist in Boston. Brian was taken off Neo-Mull Soy the middle of

August when we could not find it any longer and heard it had been recalled. He was put on another soy bean formula called Soyalac.

At the end of August we were very concerned and upset by Brian's lack of progress and requested an appointment be made as early as possible with the Pediatric Neurologist at Massachusetts General Hospital. The appointment was made for September 27, 1979. Brian's development improved within that month, his first month off Neo-Mull Soy. He was examined by Doctor Robert Delong. He called Brian's problem as "pseudo retardation" which is children lacking proper nourishment due to excessive spitting up.

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Brian is now attending The Arthur Trudeau Center (a school for Retarded and Developmentally Disabled children). Therapists work with Brian for a three hour session on Monday, Wednesday, and alternating Thursdays. Brian and I still attend Meeting Street School once a month so we as a family can learn how to help him at home.

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If you analyze the reported illnesses nationally, the one common denominator is Neo-Mull Soy. Since the FDA has scientifically proven it lacked chloride, a vital nutrient, something must be done to prevent this tragic situation from ever happening to anyone else.

This incident has caused us and our family much heartache and mental anguish. There is no margin for error in the manufacturing of infant formula.

Senator METZENBAUM. I am sure that I speak for the entire committee when I say to all of you that we appreciate the difficulty of your testifying and speaking on a subject that is obviously very much of emotional concern to every parent concerning their children. We are grateful to you for taking the time, the trouble to be with us, and to speak out on this subject. We thank all of you who unfortunately must suffer with this problem, but we join you, Mr. and Mrs. Marcantonio, Mr. and Mr. Casper, and Mr. and Mrs. Pilot, in praying that all of your children will grow up and be healthy and normal children in every way.

I have only a few questions.

Your pediatrician, as I understand it, recommended Neo-Mull-Soy specifically; is that correct?

Mrs. MARCANTONIO. Yes.

Senator METZENBAUM. When did it first occur to you that it might be the formula that was creating the problem?

Mrs. MARCANTONIO. It never occurred to me; and even with all the doctors—15 doctors have seen him now—and never one ever questioned the formula. Everything else but.

Senator METZENBAUM. When did you learn about the problem with Neo-Mull-Soy?

Mrs. MARCANTONIO. My husband heard it on television. I have a cousin in the Washington area that heard a news report down here. But again I never gave it much thought even at that time. It was not until January of this year when I got a call from another mother in Rhode Island who had heard that my baby was on Neo-Mull-Soy, and having problems, and she said, let's find out if there is anyone else who has been through what we have been through.

Senator METZENBAUM. Did the pediatric neurologist indicate that brain damage in the frontal area could be related to the Neo-Mull-Soy, or did you not ask him at this time?

Mr. MARCANTONIO. Senator, we asked the question specifically. Given the amount of fact he had in hand, the best he could tell us was that something happened to Brian when he was approximately 5 or 6 months old, and he has no idea what it is. He feels and we feel with the amount of data that is available, we just cannot pursue the issue.

Senator METZENBAUM. Did he indicate that he felt that something had happened in contrast to the possibility that Brian had been born with the brain damage?

Mr. MARCANTONIO. He felt very comfortable that Brian had not been born with it, since he saw Brian at 5 months old. He felt that, yes, he was a little bit delayed at that point, nothing to be concerned about.

The specific reason we went to him initially was to see if the brain was the cause of the projectile vomiting; and after he gave Brian a very, very thorough exam, he felt it was not.

Senator METZENBAUM. How is Brian's health and development now?

Mr. MARCANTONIO. Terrible. Physical health, excellent. You can just look at him, and he is not undernourished——

Senator METZENBAUM. He looks beautiful.

Mr. MARCANTONIO. Last year for 4 months he looked terrible. The first 4 months he was on Neo-Mull-Soy he never moved. He

stopped rolling over, and I never saw it again until he came off in September.

Senator METZENBAUM. He is making up for it here at the hearing this morning. We are happy to have him do so. He is very active.

Mr. MARCANTONIO. Although he is very active, consider his age. He does walk.

Senator METZENBAUM. How old is he now?

Mr. MARCANTONIO. 23 months. The difficulty we face is, we have a 4 year old who has been tested along with Brian so they could tell of some relationships, and he is at age six, OK? So we are seeing such a wide gap between the two of them, both growing up in the same environment, which is very discouraging.

Senator METZENBAUM. I gather it is your opinion that the problems that Brian experienced came from Neo-Mull-Soy?

Mrs. MARCANTONIO. Yes, it is. The first 3 months he progressed so well, and it was not until he went on it that he really went downhill. When he came off of it, we saw another big improvement. He was on it a total of 10 months.

Senator METZENBAUM. Brian was on it 10 months?

Mrs. MARCANTONIO. Ten months. Six months with no food.

Senator METZENBAUM. We hope that his future is a bright one and healthy one.

Mrs. MARCANTONIO. Thank you.

Senator METZENBAUM. We like his activity here at the table this morning.

Thank you for being with us.

Senator SCHWEIKER. As I listened to your statement, you testified that you put Brian through quite a few tests, mainly at the doctors' suggestions.

I would like to ask either of the parents, would you have a rough figure as to how many dollars worth of tests have been ordered on Brian? What proportion of the testing bill was covered by insurance?

Mr. MARCANTONIO. The expense in terms of dollars and cents has been minimal because of the health coverage that we do have. The expense directly that we have incurred—I really cannot tell you how much it has cost Blue Cross-Blue Shield.

Senator SCHWEIKER. Your health insurance covered Brian's testing?

Mr. MARCANTONIO. A good portion.

Senator SCHWEIKER. You have not had to spend out-of-pocket——

Mr. MARCANTONIO. It is not important.

Senator SCHWEIKER. How long was Brian on the formula, Neo-Mull-Soy?

Mrs. MARCANTONIO. Ten months.

Senator SCHWEIKER. That is all the questions I have.

Senator METZENBAUM. Thank you very much, Senator Schweiker.

Mr. Gasper, I did not give you an opportunity to speak. I did not know if you wished to add anything to what had been said. I did not mean to slight you.

Mr. GASPER. No, Senator. I do not feel slighted at all. We just wanted to come and support this law, and with the possibility of getting some help for these children, long-term help, steady pro-

gram for them, where we can find out just how severe their problems may be.

Senator METZENBAUM. Mr. and Mrs. Pilot, we are very happy to have you with us this morning.

Who will be the spokesman?

Mr. PILOT. The spokesperson today will be my wife.

Senator METZENBAUM. Thank you for the correction.

Mr. PILOT. Thank you, Mr. Chairman and Senator; thank you for the opportunity of being here.

Some of the testimony you have heard today brings the problem from the abstract to the very real. Because the mothers in particular have had to carry a heavy burden during this entire period of time that these infants were exposed to formula and problems developed, it is only appropriate that we hear from the mothers. So today my wife will describe for you what happened with our son, Bradley, who is getting his practical lesson in civics, and the science of political philosophy today.

She will also comment somewhat on the legislation that is before you today for discussion.

Senator METZENBAUM. Very happy to hear from you.

Mrs. PILOT. Exactly 1 year ago, on June 9, I began to feed Neo-Mull-Soy to my 3½-year-old son, Bradley. In only 1 month, my son began to exhibit the devastating effects of this sorely deficient infant formula.

In a period of only 8 days, Brad lost over 2 pounds from this strange malady that befell him. It took three doctors 21 days to determine that he should be hospitalized for these strange sounding symptoms.

Likewise, pediatricians across the country were unaware that many infants that they diagnosed as "failure to thrive" were in this state due to the infant formula that had been prescribed for them.

My son was actively very ill for 42 days. While he was hospitalized, he was poked, prodded, hooked up to EKG's, IV's; had blood painfully extracted every few hours until the only place left was his jugular vein. His formula caused irregularities of the heart, liver, kidneys, adrenal gland, gross abnormalities of the blood, skin tissue, muscle tone, and numerous other problems. We still do not know what the long-term effects will be.

In my opinion, there is little doubt that 20th-century technology and Government regulation failed a large number of infants and parents in the United States. An industry dedicated to the growth and development of infants couldn't meet their own expectations; and the agency whose responsibility it is to safeguard the public health failed us miserably; and the physicians who are expected to cope with the awesome burden of properly diagnosing and treating infant ailments were not able to recognize the problems confronting them.

Because, like thousands of other infants across the country, my son was made to suffer so intensely, because all of our families lived this nightmare, and because we, as parents, cannot morally let this incident pass without attempting to remedy situations like this, we are here today.

My friend, Carol Laskin, who is the mother of another affected child—and I have received hundreds of letters from mothers across our country whose children were also devastated by this formula—I believe I speak for them and with them when I ask that legislation requiring the mandatory systematic testing of infant formula for each required nutrient substance be passed by the Congress. The Infant Formula Council claims that industry has built systems which assure that each batch achieves the desired quantity of each of the added nutrients. However, we know from this and other sad experiences that this is not always the case.

Although industry apparently supports necessary ingredient testing, they feel that no true public interest is served by following a system requiring the submission of data and its review and approval by an administrative agency.

We, on the other hand, feel that a systematic routine testing program must be mandated by Congress to insure that the necessary tests are, in fact, being performed.

We, therefore, concur with the intent of the Senate legislation as introduced by Senator Metzenbaum. This legislation, which calls for testing and requires notification rather than approval by the FDA would put the manufacturers on record as having performed all vital procedures under penalty of law.

Although the House bill, H.R. 6940, claims to have cured the evils previously mentioned, it does not legislatively provide for the routine testing of infant formula. Instead, it merely thrusts this problem back upon the FDA and asks that the agency promulgate regulations to establish quality control procedures. By their own admission, this may take years to accomplish.

Under House legislation, there are only two instances when an infant formula manufacturer must notify the Secretary: (1) prior to marketing a new infant formula, and (2) when there has been a reformulation or a change in the processing which "the manufacturer reasonably determines may affect whether the formula is in compliance."

Here we object on two grounds:

First, that it is still the manufacturer who ultimately determines whether the change in formulation is major enough to fall into the category, e.g., Syntex's failure to test after the removal of salt, sodium chloride, because salt is supposedly only a minor constituent; and, second, if thorough testing is not done on a routine basis, how would a mechanical malfunction or processing error be discovered?

The proponents of the House bill feel that all errors will be caught by the mere fact that FDA now has the authority to enter a manufacturing facility and check certain records. Here we ask, "How frequently must the FDA actually make inspections?" Nothing is stated in the proposed House legislation. Even in the case of drugs and certain medical devices, the FDA must inspect only once every 2 years. What is the minimum requirement with respect to infant formula?

We believe that with stringent, required testing procedures, parents can again have confidence in the quality and nutritional adequacy of infant formula.

If FDA is to effectively implement the intent of Congress with respect to the safety and effectiveness of all infant formulas, then it must have a clear and comprehensive statutory base.

The Senate legislation provides many of the basic tools necessary for the FDA to build and maintain an effective machinery for regulating these products. The House bill likewise contains some explicit and implicit provisions designed to assure the safety and effectiveness of infant formulas.

We believe that FDA should have specific statutory authority over infant formulas comparable to that which it now possesses for pharmaceuticals and important medical devices. These formulas are much too important to warrant anything but the most comprehensive statutory base.

In this respect, we hope that FDA will be in a position to maintain an accurate list of manufacturers and the formulas they manufacture so that proper surveillance can be conducted by FDA.

We agree that manufacturers should be required to notify FDA of any report which may involve a possible hazard to health, adulteration or misbranding irrespective of whether a decision to voluntarily recall the infant formula is made by the manufacturer. The FDA should have the responsibility to determine whether a recall is necessary and the authority to require a manufacturer to recall a product if FDA determines it is beneficial to the public. FDA should also have the flexibility to determine the scope and depth of the recall. In addition, manufacturers should be required to maintain a file of all complaints and make this file readily available to FDA on request.

There are two other specific areas where we believe it would be useful to consider simple modifications to the House and Senate bills. These relate to requirements for standards for nutrient levels and good manufacturing practices (GMP's) over and above those procedures which relate to testing and quality control.

The legislation should officially recognize the recommendations of the American Academy of Pediatrics Committee on Nutrition until the FDA has by regulation developed standards necessary to assure the safety and effectiveness of infant formulas.

Because, by FDA's own admission, the promulgation of regulations is a lengthy process, why not merely accept the work done by professionals in private enterprise—here the Committee on Nutrition—and spare the Government the overwhelming burden of trying to keep pace with the state of the art?

There is a precedent for this approach with respect to standards for drugs which are developed by the U.S. Pharmacopeia. Additionally, in the area of medical devices, the FDA has expressed its intent to rely heavily on the private sector to develop standards.

The FDA should have the authority to require compliance with applicable GMP regulations. The GMP's should require, among other things, appropriate process controls, end-product testing and a quality control and audit program to assure that the product as processed meets manufacturers' specifications. Clearly, it was the absence of this kind of a rigid and proper system that resulted in Syntex's failure to manufacture a safe infant formula. This kind of omission, commission, or human error, should never be permitted to occur again.

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The last suggestion we would like to make about the legislation is that the FDA should have unqualified access to any and all records relating to research and development of an infant formula for commercial or special marketing; the manufacture and distribution of infant formula, including any record necessary to assure and verify compliance with GMP's; complaint files and any other records bearing on whether the infant formula is adulterated or misbranded. All of these records should be maintained for at least the shelf life of the infant formula.

We believe it is essential that FDA have the statutory authority described above if it is to properly regulate these life-sustaining, life-supporting, and growth-essential infant formulas. Legislation which encompasses these requirements will provide the FDA with the type of statutory authority that appears to be reasonable in light of the experience of the last year.

More important than this, however, is the need for FDA to respond with a reasonable and effective program that implements these authorities.

The FDA has neglected to do this in the past, and we are concerned that it will relapse into a state of dormancy if it is not totally committed to this objective or constantly prodded by crisis to do what should be done.

The FDA needs to inspect firms on a regular basis, conscientiously review what is acquired through inspection or by submission, and assure that all labeling and advertising information relative to infant formulas is honest, accurate and not otherwise misleading.

For example, there are formulas that have carried and continue to carry statements to the effect that "The nutrient levels meet Food and Drug Administration requirements for infant formula."

If FDA is a decade behind the expectations of users, what does a statement like that mean? We know from sad experience that 1 year ago, Syntex could have labeled its products with this statement and it would have been true. Irrespective of the outcome of this legislation, FDA must make a commitment to followthrough on a regular basis. If not, the public will lose confidence in the very agency designed to safeguard them from worthless or harmful products.

Clearly, Congress can provide the necessary oversight to assure that this doesn't happen, but ultimately the real solution to this problem is within the control of the industry and health professions.

If there are legitimate questions about the scientific issues that relate to infant nutrition, then the medical and scientific communities have a responsibility to debate the issues, crystallize the questions to be answered and pursue a course of scientific inquiry that will restore and enhance public confidence in those professionals whose responsibility it is to care for those who represent our future.

Finally, the infant formula industry must recognize that in spite of its best intentions, conditions will never be as they were prior to the Syntex recall. If the industry is truly committed to manufacturing and marketing only the highest quality infant formulas and if it is committed to the principles expressed by its trade association, the Infant Formula Council, the legislative and administra-

tive relief that the parents across the country are demanding is not unreasonable. We trusted the industry and expected that they would provide well for us.

They failed and, while our passion as parents may be to emotionally cry out for punishment, we believe the natural patience and restraint that we must exercise as parents leads us to conclude that some reasonable assistance from Congress and FDA may be more helpful in the long run.

We want to have confidence in the manufacturers of infant formulas and we don't want the costs of these products to increase because of unreasonable laws or unwise regulatory programs. We believe that the requests we are suggesting will not impose unreasonable or costly burdens on the industry and that these authorities will enable the FDA to know who is manufacturing what formulas, what they are saying about them, and how they are developing, manufacturing, and marketing these products to the public.

For the infants who will be replacing us in the future, I do not believe this is too much to request.

In conclusion, we feel that the Senate legislation is a step in the right direction. We would, however, like to see the testing provisions spelled out in greater detail to encompass all vital aspects and the incorporation of some of the principles we outlined.

Right now, Senators, you are our only hope. We mothers are really not asking for much—just an insurance policy so to speak. Since there is no food as important in life as the food an infant consumes, we owe these little Americans the guarantee that their sole subsistence be truly safe and nutritious.

Thank you.

Senator METZENBAUM. Thank you very much, Mrs. Pilot, for a very excellent statement, covering the legislation as well as the problems as you know them to be.

You are not only a good legal student of our legislative process, and we appreciate your support for the Senate approach, but we also appreciate the fact that you bring to the legislative process a perspective not only of a mother, but of a leader in an organization that has taken a special interest in this subject.

Would you tell me the name of your organization, if it has one?

Mrs. PILOT. Actually, we do not really have a name for it. We call ourselves Formula. We have a box number, et cetera. That is how people contact us throughout the United States.

Senator METZENBAUM. How do people find out about you? How do we find out how to write to Formula?

Mrs. PILOT. We have really embarked upon many programs whereby we have been sending letters to editors. We have been trying to get the media to pay attention to this fact.

The reason we want for parents to be made aware of this is so that they will know what is going on. As I said, very few people know what has happened.

As far back as a few weeks ago, people were finding out for the first time that maybe this had some bearing on why their child was hospitalized, why their child was so terribly ill. We are solely relying on the goodwill of the media to broadcast our message, so

to speak, so that we can gather the people in and attempt to help the infants and their parents.

Senator METZENBAUM. How many letters have you received, would you say?

Mrs. PILOT. There are hundreds and hundreds and hundreds of letters.

Senator METZENBAUM. What is the address of Formula?

Mrs. PILOT. It is Formula, Box 39051, Washington 20016.

Senator METZENBAUM. The Center for Disease Control has come out with a figure indicating there is something like 130 infants who have been affected by formula problems.

Would you agree with that figure?

Mrs. PILOT. I think they have 130 documented cases, meaning these children were fortunate to have while hospitalized, to have electrolyte and blood gases tests. Many infants were hospitalized, but no one did electrolytes and blood gases. Doctors did not know what they were looking for. They were running cystic fibrosis tests, kidney biopsies, but oddly enough, electrolytes and blood gases are not routinely run on children.

Senator METZENBAUM. What is that test?

Mrs. PILOT. Electrolytes and blood gases.

Senator METZENBAUM. Electrolytes and blood gases.

Mrs. PILOT. Yes. We were fortunate enough to walk in a hospital and ask for these tests because there was a little article in the New York Times the day before the baby went to the hospital indicating there might be a problem with Neo-Mull-Soy, indicating development of metabolic alkalosis.

I called my pediatrician and said, maybe my baby has metabolic alkalosis. He said, my goodness, no. Your baby does not have symptoms of that.

When we went into Childrens Hospital here in Washington and they checked the baby from head to toe, we asked for the diagnosis and they said, we have no idea. We said, would you do us a favor? Would you give electrolytes and blood gases and see if it is metabolic alkalosis. I am sure they thought we were out of our minds.

They did. And that was it.

Senator METZENBAUM. Actually, the test was made only because you insisted that the test be made?

Mrs. PILOT. Yes, sir. Eventually, they might have gotten to it, but we were fortunate enough to have it done right away because we asked.

Senator METZENBAUM. How old is Brad now?

Mrs. PILOT. Fifteen months old.

Senator METZENBAUM. How is he doing?

Mrs. PILOT. He appears to be very healthy, as you can see from his physical stature.

Senator METZENBAUM. As I can hear, too.

Mrs. PILOT. He has developed mentally slow. We have him enrolled in a program for children who have developmental problems now and handicapping problems. He has come a long way in just the past 2½ months. At 1 year, he was not doing what he should have been doing also. He at that time began to crawl and pull himself up. He just recently began to walk, and he is doing very well.

Senator METZENBAUM. That is great.

Have any of you heard from any of the formula manufacturing companies?

Mrs. MARCANTONIO. Someone from Syntex called one of the other mothers in Rhode Island, had her phone number, but my name, and asked her what our group was doing in Rhode Island; and if there were any further problems to make sure pediatricians did notify Syntex.

Senator METZENBAUM. That is the only time you have heard from them?

Mrs. MARCANTONIO. Yes.

Senator METZENBAUM. How about you, Mrs. Gasper?

Mrs. GASPER. No.

Senator METZENBAUM. You have not heard from the formula company?

Mrs. GASPER. Have not.

Senator METZENBAUM. And the Pilots; have you?

Mr. PILOT. Yes. I have had some correspondence with them and some conversations with them as well.

Senator METZENBAUM. What do they say? What is their position? Do they acknowledge the problem?

Mr. PILOT. There is no question they acknowledge the problem. They have done that publicly, and they are not about to suggest to the public that they were not responsible for manufacture and distribution of a defective formula. The conversations that I have had with them have touched on that and other issues relating to compensation for damages, future considerations.

The company did contact us as a matter of fact when Bradley was in the hospital, after I initiated a call to the firm, to inquire of them what the nature of the problem was. As Lynne mentioned, we first learned of the possible nexus with respect to the article that appeared in the New York Times. I called Syntex and inquired of them what the problem was.

Senator METZENBAUM. If the television cameramen did not catch that, you missed the best part. He is very smart, because he poured it on the Gaspers and not on his own parents.

Mrs. PILOT. It is only on the floor.

Senator METZENBAUM. Excuse me, Mr. Pilot.

Senator SCHWEIKER. You have been upstaged.

Mr. PILOT. I was commenting on the conversation I had with Dr. Ingram of Syntex who revealed to me at the time—and this is why we had Bradley at Childrens Hospital—what the nature of the problem was; and he spoke to the pediatricians in Childrens Hospital, National Medical Center, to advise them of what some of the symptoms were and what kind of diagnostic procedures to employ in order to determine whether or not Bradley was suffering from metabolic alkalosis.

Mrs. PILOT. Their recommendation was that we merely change his formula, and he would get better. In our case, he did not. He got worse. He was so sorely lacking in the necessary chloride, et cetera, so he had to go on IV's.

Senator METZENBAUM. Mr. Pilot, you were formerly an attorney at FDA?

Mr. PILOT. I am an attorney in private practice now. I had been with the Food and Drug Administration for 10 years in the Bureau of Medical Devices where I was in charge of all of our compliance activities.

Senator METZENBAUM. Do you subscribe to the comments of Mrs. Pilot concerning legislative approach?

Mr. PILOT. Yes; we had some discussion about her comments and some areas where we agreed and disagreed; but I subscribe to the comments that she made in that testimony. I certainly believe, as has been emphasized many times this morning, these infant problems are probably the most important source of nutrition that people—and these are people who grow up someday to replace us in rooms like this—will ever consume. If that food is not nutritious, to provide them with the type of nutrients they need in order to develop properly, there will be subsequent problems of the type that result in burdens to society. Therefore, if these formulas are that important, if they are that important, FDA, in our opinion, should have statutory authority comparable to that which is now exercised over drugs and certain medical devices.

Senator METZENBAUM. Senator Schweiker?

Senator SCHWEIKER. Mr. Pilot, how long was Bradley on the formula?

Mr. PILOT. Bradley was on approximately 8 weeks, from the beginning of June to the end of July.

Senator SCHWEIKER. After Bradley got off the formula, what kind of changes did you notice?

Mr. PILOT. His appetite improved. His weight began to increase. He was no longer dehydrated. He did not display any of the physical symptoms that he displayed before. Again, Bradley was 6 months old at the time, or 5 months.

Senator SCHWEIKER. Did your medical insurance cover most of Bradley's medical expenses during this period, or not?

Mr. PILOT. Yes, for the most part.

Senator SCHWEIKER. Mrs. Pilot, you mention in your testimony that you feel we should include, in the legislation itself, the specific nutrient composition for infant formulas, published by FDA as interim guidelines, which I believe is based on the pediatrics——

Mrs. PILOT. I do not believe I said that. I think what I recommended is that——

Senator SCHWEIKER. Please state what you recommend.

Mrs. PILOT [continuing]. That is the American Academy of Pediatrics, Committee on Nutrition, who establishes these guidelines in the first place; and it is the FDA who, by regulation says, yes, we will use these. However, there had been a big lapse in time between the time when AAP comes out with these and the FDA actually comes out with regulations. We were going according to the 1971 regs until this year, and that is almost a 10-year lapse.

What I was suggesting is, since they do make or establish the nutrient levels to begin with, why not accept their nutrient levels as the nutrient level according to law unless FDA, by regulation or, I should say, until FDA, by regulation, changes it, or establishes it, et cetera. I think there is precedent for this, because, with drugs, the U.S. Pharmacopeia, which is an outside concern, does the same thing.

Senator SCHWEIKER. I was going to say that I thought the interim guidelines were based on American Academy of Pediatrics' recommendations. You are saying there is a timelag here and that there is a difference between the FDA's proposed interim standards and the recommendations of the American Academy of Pediatrics?

Mr. PILOT. Yes; I do not know if FDA or the Infant Formula Council plans to discuss that; but FDA does have statutory authority to require certain labeling requirements for food, such as infant formula. FDA did recognize the 1971 recommendations of the Academy of Pediatrics, Committee on Nutrition. Those regulations continue to be in effect.

However, the academy, in 1976, modified their minimum nutrient requirements to include, among other things, a range for chloride. FDA did not modify their regulations. So the regulation that is in effect today is one that reflects the 1971 state of the art.

Now, Lynne mentioned that FDA earlier this year had taken a different position. I presume that FDA will discuss this. But FDA did publish notice in the Federal Register indicating to industry that they should use for guidance purposes the recommendations, the 1976 recommendations of the American Academy of Pediatrics. Those recommendations, I believe, essentially reflect the nutrient levels that are present in the House bill, identified in the House bill.

Senator SCHWEIKER. That is my next question. I refer to the interim guidelines which were published by FDA on March 18 of this year.

Do those interim standards reflect the necessary chloride levels, or not?

Mr. PILOT. As guidelines, they do.

Senator SCHWEIKER. I strongly concur that we should have language in the bill specifying a nutrient list, once we can resolve controversy over what is the most up-to-date, scientifically valid set of recommendations.

Thank you.

Senator METZENBAUM. Thank you very much, Senator Schweiker.

Again, thanks to the Pilots, Gaspers, and Marcantonios.

Mr. MARCANTONIO. I would like to ask a question.

Senator METZENBAUM. Sure.

Mr. MARCANTONIO. A number of times today, I have heard the number of 130 as the number of documented incidents of children across the country that have experienced problems.

Senator METZENBAUM. Yes.

Mr. MARCANTONIO. One of the interesting things that we are aware of, particularly in Rhode Island, we do not know of any doctors in Rhode Island that have ever been notified that there was a problem with this formula.

You asked the question earlier: Was the formula recommended to us by our physician; and yes, it was. We, through my wife and friends of hers, have provided all of the literature that we have been able to acquire, to the physicians locally. So the number 130, the first question I have is: How old is that number? And what would the number be today; and, second, what would the number be if physicians were aware of the degree of the problem?

Senator METZENBAUM. We understand your point, Mr. Marcantonio.

The American Academy of Pediatricians will be testifying later this morning, and the Center for Disease Control as well, and we will get into that with them.

Mr. MARCANTONIO. Thank you.

Senator METZENBAUM. Thank you all very much. We are very grateful to you, as well as the supporting cast.

Our next witness is Jere E. Goyan, Commissioner, Food and Drug Administration.

Dr. Goyan, we are happy to have you with us this morning. Your entire statement will be included in the record. I wonder if you would be inclined to summarize it orally, which is not an unusual procedure before legislative committees.

STATEMENT OF HON. JERE E. GOYAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY NANCY L. BUC, GENERAL COUNSEL, FOOD AND DRUG ADMINISTRATION

Dr. GOYAN. Thank you very much, Senator Metzenbaum. It is a pleasure to be here with you this morning.

I have on my right Ms. Nancy L. Buc, Chief Counsel of the Food and Drug Administration.

I will leave out the steps that we have already taken with regard to this matter and go on to talk about our legislative authority.

Unfortunately, there are two very large gaps in our legislative authority in the area of foods. The foremost of these gaps is our lack of authority to inspect and review manufacturers' quality control and distribution records to determine whether manufacturers are in full compliance with the law and, if not, to locate any violative product as quickly as possible. Another is the need for explicit statutory authority to require quality-control procedures so that we can take action against interstate shipments of formulas that are not produced in compliance with such procedures. This is the nub of the problem that we have heard described by the parents that preceded me.

Therefore, under quality control, we would like to see the bill amended to provide specific legislative authority for the Secretary to establish quality control requirements for the production of infant formulas. Since infant formulas can be the sole source of nutrition for many infants, it is certainly essential that good quality-control practices be followed. If they are not, we get the sort of tragedy we heard.

Senator METZENBAUM. We agree with that approach.

Dr. GOYAN. Notification requirements: We strongly oppose the provisions of the bill that would exclude as evidence in a proceeding to enforce the act information required to be contained in such a notification.

Senator METZENBAUM. You strongly oppose; is that what you said?

Dr. GOYAN. Yes, sir, we oppose the idea that we would exclude as possible evidence information that they had made available to us at that time.

Senator METZENBAUM. Explain that.

Dr. GOYAN. Our concern is that merely because a manufacturer has told us that they have a problem; that should not exculpate them from that particular problem.

Under recordkeeping and inspection: Other provisions of S. 2490 are also valuable, especially those that would require processors to make and retain distribution records, and would permit the Department to examine and copy such records. These provisions would greatly facilitate the implementing and monitoring of recalls and seizures because these records can be used to trace the course of the product through the distribution chain.

We also support the provisions of S. 2490 that would increase the Department's access to other records of infant formula processors.

One of the most serious impediments to effective enforcement of the food laws is the Department's relatively narrow records inspection authority. Certain violations, such as those related to the use of ingredients, can be discovered only by reviewing records. In other cases, proof of violations would be simplified if records could be inspected.

In this regard, I should note that FDA has developed, as part of its efforts to improve the regulation of infant formulas, a compliance program with a permanent surveillance system of infant formula nutrient composition.

This program will go into effect in fiscal year 1981. If Congress provides additional inspection authority, this intensified inspection coverage would clearly assist us in making certain that firms are putting into place the required quality assurance procedures.

ENFORCEMENT

S. 2490 would also provide the Department with the authority to detain infant formulas suspected of being adulterated or misbranded in accordance with regulations prescribed by the Secretary. This is a useful enforcement mechanism because it prevents the further movement of suspected products in interstate commerce. Detention authority, coupled with the increased recordkeeping and inspection authorities provided in the bill, will significantly strengthen our enforcement capabilities.

We do have some problems with S. 2490.

While many of the provisions of this bill would strengthen the Department's regulatory authority over infant formulas, we cannot support the following provisions discussed below.

LABELING

We believe that the entire section on labeling is premature. The labeling issues and recommendations in the bill need further study and consideration before they are established by statute. Several of the labeling provisions relating to indications for use and proper storage conditions are important. Other provisions need further careful consideration to determine their usefulness or feasibility before they are set into law.

Senator METZENBAUM. Why do you distinguish infant formula and the need for labeling there; whereas, with respect to many other products, you do have labeling and you live with it very well? Why do you have to study this further?

Dr. GOYAN. For example, Mr. Chairman, there is a part of the bill that discusses color coding, whether infant formula should be diluted with water. We are not at all sure that this will work effectively. We are presently doing some studies on labeling because of our interest in food labeling in general. We are looking for the best ways of bringing this sort of information to the attention of the parents.

Senator METZENBAUM. How long have you been looking at the problem?

Dr. GOYAN. We started this particular effort about a year ago, I believe.

Senator METZENBAUM. How many more years do you think you need to study it?

Dr. GOYAN. I would expect we would have some good information within the year.

Senator METZENBAUM. Within the year?

Dr. GOYAN. Yes.

Senator METZENBAUM. If that is normal, bureaucratic response, 1 year means 3, and then you would probably appoint a commission to study it. I think the committee would like to have you tell us very specific reasons whether today or at another time why you oppose labeling since I must say to you I have difficulty in understanding why that requires so much study. I am not sure, doctor, that you have convinced me as of this moment.

Dr. GOYAN. I will be glad to provide additional information for the record, Senator.

Senator METZENBAUM. Thank you.

Senator SCHWEIKER. Do you have the authority now to publish labeling requirements for this formula?

Dr. GOYAN. To require labeling?

Senator SCHWEIKER. Yes.

Dr. GOYAN. Yes.

Senator METZENBAUM. But you have not done it?

Dr. GOYAN. We have done a good deal——

Senator METZENBAUM. On other substances.

Dr. GOYAN [continuing]. On infant formula as well.

Ms. BUC. We do have authority to require information when absence of that kind of information would be misleading to the consumer. We use that routinely in a number of different areas. We have used similar authority to require the disclosure on labels of infant formula of what the vitamin and mineral content is, the issue you were discussing a minute ago with the Pilots. We do have authority to require information on labeling; yes.

Senator METZENBAUM. In one sentence, tell me why you are opposed to requiring labeling. I am not clear. I cannot understand why you are opposed to it.

Dr. GOYAN. We think there are too many labeling aspects in the bill at the present time.

Senator METZENBAUM. Too many specific aspects?

Dr. GOYAN. Let me take one point.

There is the requirement that there be a statement to the effect that breast feeding is preferable to infant formula. I personally have problems with that because I think it is terribly unfair to a parent who has to use infant formula, to have to see that on the

can each time she prepared the formula and feel that somehow she is doing second best for her child.

Senator METZENBAUM. Have you taken any action against Abbott Ross that already has that statement on their formula?

Dr. GOYAN. No, sir.

Senator METZENBAUM. If you think it is that wrong, you would have authority to take such action if you thought it was wrong?

Dr. GOYAN. I do not believe so. I do not believe we could take action against it.

Senator METZENBAUM. Assuming you have difficulty with that particular statement, are there other problems?

Dr. GOYAN. There is another "precautions to be taken during use of product and side effects and adverse reactions that may result from improper use of the product." I think that is more properly done by the physician. We strongly support that part of the bill that relates to labeling for the professions.

Senator METZENBAUM. Do you require that with respect to pharmaceuticals now?

Dr. GOYAN. With regard to prescription drugs, we do.

Senator METZENBAUM. You require that kind of labeling? Dr. Goyan. We require it for physicians and we are in the process of doing similar things for patients, yes.

Senator METZENBAUM. You would not require it for formula, but you would require it for pharmaceuticals? Why?

Dr. GOYAN. Because we think pharmaceuticals are more of a problem in this particular case.

Senator METZENBAUM. More of a problem?

Dr. GOYAN. In the sense that you have said here that side effects and adverse reactions—I think they are much more common in prescription drugs than they would be in this case.

Senator METZENBAUM. Please proceed.

Dr. GOYAN. I would be glad to make more information available on that as well.

[The following was received for the record:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

STATEMENT

BY

JERE E. GOYAN

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

JUNE 12, 1980

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

Thank you for asking me to testify today on two bills that would increase our regulatory authority over infant formulas. Each bill is cited as the "Infant Formula Act of 1980." S. 2490 was introduced in the Senate by Senator Metzenbaum, and H.R. 6940 was introduced in the House by Representative Waxman. The Waxman bill was passed by the House on May 20, and referred to this Subcommittee.

BACKGROUND

Infant formulas are uniquely important food products that often provide an infant's sole source of nourishment during the critical first months of life. Formulas must be nutritionally sound, highly digestible, free of pathogenic organisms, and labeled with easily understood instructions. Because an infant's health and normal development depend on the quality of nutrition supplied by these formulas when used as a sole source of nutrition, there is no margin for error in their composition and production. These formulas also play a significant role in infant nutrition when supplemented with other foods. By virtue of their unique and often critical role in human nutrition, infant formulas are, in our view, a proper subject for special attention.

Last summer a problem arose with infant formulas manufactured by Syntex Laboratories, Inc. of Palo Alto, California, when a deficiency of chloride, an essential nutrient, caused serious illnesses among infants being fed either Neo-Mull-Soy or Cho-Free formulas as their sole source of nutrition.

This deficiency-induced illness, known as metabolic alkalosis, was characterized by a loss of appetite, failure to gain weight, lethargy, and constipation. When the infants were taken off the defective formulas, they began recovering and, as far as is currently known, there is no conclusive evidence of any long-term adverse effects. However, the National Institutes of Health (NIH), in collaboration with the Center for Disease Control (CDC) and the Food and Drug Administration (FDA), is now conducting followup studies among these children to detect any biochemical or developmental abnormalities. A number of pediatricians also are following their affected patients carefully.

The Neo-Mull-Soy/Cho-Free problem was compounded by an incomplete recall of these infant formulas. In October of 1979 press reports revealed that some cans of the defective formulas were still available in certain retail outlets two months after the recall had been announced. In addition, as recently as February 19, 1980, at FDA's open public meeting on infant formulas, it was learned that limited numbers of these products were still on the retail market in some stores in the State of Missouri. These discoveries raised serious questions about the effectiveness of the Syntex recall and the adequacy of FDA's procedures for monitoring the recall.

ADMINISTRATIVE ACTIONS

Over the last several months, FDA conducted a thorough review of its administrative and statutory authority to determine what steps are needed to insure the safety and nutritional quality of infant formulas and improve its recall procedures. Using our existing authority:

-- We have revised our general recall procedures to establish better coordination between headquarters and district offices. Under these revised procedures, which were distributed to field and headquarters staff in February 1980, FDA will conduct its own audit checks of a firms' effectiveness in conducting all class I and class II recalls (not just infant formula recalls).

-- We held two public sessions on proposals to strengthen our regulation of infant foods: the first was a public meeting on February 19, which focused on manufacturing and processing of infant formulas plus the testing of and nutritional quality assurance of reformulated products; the second was a public hearing on March 12, which concentrated on the nutrient composition of infant formulas and the need for any changes in current FDA nutritional requirements. In preparation for these sessions, we contracted with the Federation of American Societies for Experimental Biology (FASEB) to prepare a background paper on infant formulas. That study has been extremely helpful in assessing the infant formula situation. We have a copy of the FASEB paper for the record.

-- We have analyzed the reformulated products prepared by Syntex and our tests confirmed that they were in accord with the nutrient guidelines of the American Academy of Pediatrics (AAP) and FDA regulations covering infant foods. On December 17, 1979, we notified Syntex's management of these results and informed them that it would be appropriate to reinstitute commercial distribution of the reformulated products.

-- We have begun an educational initiative on the recall process to alert retailers, and particularly pharmacists, about the importance of recalls.

-- We have completed a 3-month survey of the nutrient content of infant formulas and tested 29 products made by 6 manufacturers, Gerber Products Company, Loma Linda Foods, Mead Johnson and Company, Ross Laboratories, Syntex, and Wyeth Laboratories. This represents over 95 percent of the infant formulas being marketed today. Twenty-eight of these products posed no problems in terms of nutrient content. However, FDA's analysis showed a sample of I-Soyalac, made by Loma Linda, to be lower in chloride content then the level recommended by the AAP, which is the nutrient standard for infant formulas advocated by FDA. Our health hazard evaluation team reviewed this matter and concluded that, even though the chloride level was below the AAP recommendations, the products still were safe for consumption by infants. The manufacturer was informed of our findings and advised us that they were aware of the problem and already had taken the necessary steps to correct the problem.

-- In the Federal Register of March 18, 1980, we published interim guidelines for nutrient composition of infant formulas. This notice informed manufacturers that we were in the process of revising existing infant formula nutrient composition regulations and, until that was accomplished, they should follow the recommendations made by the Committee on Nutrition of the American Academy of Pediatrics in 1976. We have a target date of August 1980 for the publication of proposed revisions to our regulations for infant formula composition. We are on schedule for that regulation-making procedure. We are also preparing proposed regulations for quality assurance and quality control in the manufacture of infant formulas and expect to publish these in December 1980.

-- We have met with concerned individuals and groups and explained what has been done to correct the chloride-deficient infant formula problem and to determine if there are any long-term effects which may result.

In addition to these administrative steps, many of which will also expand our regulatory effectiveness over all other product areas, we have given serious and careful consideration to a range of alternatives for regulating the quality and production of infant formulas.

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LEGISLATIVE AUTHORITY

Although the administrative steps previously described will tighten our supervision of the manufacture and distribution of infant formulas, as well as our ability to monitor recalls, if need be, there are significant gaps in our statutory authority for all foods, gaps that particularly apply to infant formulas. We have pointed out these gaps in the past, and requests for appropriate revisions have been part of the Administration's omnibus Food, Drug, and Cosmetic Act amendments for some time. The Administration has reiterated these requests when it submitted the "Food, Drug, and Cosmetic Amendments of 1980" on April 2 to the Congress for consideration.

The foremost of these gaps is our lack of authority to inspect and review manufacturers' quality control and distribution records to determine whether manufacturers are in full compliance with the law and, if not, to locate any violative product as quickly as possible. Another is the need for explicit statutory authority to require quality control procedures so that we can take action against interstate shipments of formulas that are not produced in compliance with the regulations setting nutrient quality as well as those setting sanitation standards. But even these amendments would not provide us with all the authority necessary to regulate effectively infant formula manufacturers and to assure that product recalls are expeditiously carried out.

INFANT FORMULA BILLS

The bills before the Subcommittee today also propose to supplement our current statutory authority. We support their general intent and objective. In the following sections, we comment on the major provisions of S. 2490 and a provision in H.R. 6940 that we strongly oppose.

NUTRIENT COMPOSITION

The Infant Formula Act of 1980 (S. 2490) would require the Secretary to establish by regulation a "standard of identity and quality" for infant formulas which would include a statement of minimum and maximum levels of required nutrients.

We agree that it is important that the Secretary have authority to specify the nutrient composition of infant formulas. However, we do not believe that directing the Secretary to establish "a standard of identity and quality" for infant formula is the appropriate way of achieving this goal. Use of the terms "standard of identity and quality" should be deleted from the bill because it may unnecessarily cause confusion with the "standard of identity and quality" criteria already found in section 401 of the Federal Food, Drug, and Cosmetic Act and the procedural requirements of section 701(e) of the Act that apply to standards of identity. These terms have specific meaning under the Act and usage of the same terms might inadvertently trigger these formal procedures.

Therefore, we strongly recommend that the bill be modified to delete such reference and to authorize the Secretary to prescribe the nutrients and nutrient levels of infant formulas by regulation. This regulatory flexibility would allow advances in knowledge to be quickly applied through informal

rulemaking. We also believe it is not appropriate to require the Secretary to set maximum levels for every mandatory nutrient. This requirement should be deleted because in some cases the knowledge base for authoritatively establishing maximum levels for some nutrients is insufficient and for others there is no safety problem. We would prefer a provision that allows the Secretary to determine when to set appropriate maximum levels for nutrients.

We support the provision that would allow the Secretary to exempt from these requirements, infant formulas specially formulated for babies with metabolic or other health problems. This authority is important because these infants have requirements that differ from normal babies. However, FDA would continue to monitor these products to assure that they are safe.

The bill should also be amended to provide specific legislative authority for the Secretary to establish quality control requirements for the production of infant formulas. Since infant formulas can be the sole source of nutrition for many infants, it is essential at a minimum, that good quality control practices be followed to insure adequate amounts of nutrients will be provided.

TESTING REQUIREMENTS

We support the bill's requirement that processors of infant formulas conduct tests and make reports as necessary to demonstrate to the Secretary's satisfaction that their products comply with nutrient composition requirements. However, we believe that the timetable for submission of reports and test results to the Secretary should be left to regulation.

NOTIFICATION REQUIREMENTS

We strongly support the provisions of the bill requiring processors of infant formulas to notify the Secretary of recalls and of information indicating possible adulteration or misbranding. This is an important provision because firms often learn about such potential problems before the Agency does. However, we strongly oppose the provision of the bill that would exclude as evidence in a proceeding to enforce the Act, information required to be contained in such a notification. As you are aware, corporations do not possess the constitutional protection against self-incrimination afforded by the 5th Amendment of the Constitution to individuals. We believe it inappropriate to provide a corporation extraconstitutional protection in a situation where its actions may have placed the public health at risk.

The bill as drafted would require processors to notify the Secretary of any change in the formulation or processing of an infant formula. We do not believe that it is necessary to report every change because many changes may be made that have no health significance. The bill should be amended to provide the Secretary with authority to establish by regulation those changes in formulation or processing that must be reported by the manufacturer to FDA.

RECORDKEEPING AND INSPECTION

Other provisions of S. 2490 are also valuable, especially those that would require processors to make and retain distribution records, and would permit the Department to examine and copy such records. These provisions would greatly facilitate the implementing and monitoring of recalls and

seizures because these records can be used to trace the course of the product through the distribution chain. We also support the provisions of S. 2490 that would increase the Department's access to other records of infant formula processors. One of the most serious impediments to effective enforcement of the food laws is the Department's relatively narrow records inspection authority. Certain violations, such as some of those related to the use of ingredients, can be discovered only by reviewing records. In other cases, proof of violations would be simplified if records could be inspected.

In this regard, I should note that FDA has developed, as part of its efforts to improve the regulation of infant formulas, a compliance program with a permanent surveillance system of infant formula nutrient composition. This program will go into effect in Fiscal Year 1981. If the Congress provides additional inspection authority, this intensified inspection coverage would clearly assist us in making certain that firms are putting into place the required quality assurance procedures.

ENFORCEMENT

S. 2490 would also provide the Department with the authority to detain infant formulas suspected of being adulterated or misbranded in accordance with regulations prescribed by the Secretary. This is a useful enforcement mechanism because it prevents the further movement of suspected products in interstate commerce. Detention authority, coupled with the increased recordkeeping and inspection authorities provided in the bill, will significantly strengthen our enforcement capabilities.

PROBLEMS WITH S. 2490

While many of the provisions of this bill would strengthen the Department's regulatory authority over infant formulas, we cannot support the following provisions discussed below.

LABELING

We believe that the entire section on labeling is premature. The labeling issues and recommendations in the bill need further study and consideration before they are established by statute. Several of the labeling provisions relating to indications for use and proper storage conditions are important. Other provisions need further careful consideration to determine their usefullness or feasibility before they are set into law. Therefore, we would recommend that the entire section on labeling be deleted from the bill.

EXPORTS

The basic problems in developing countries are preparation of infant formulas under unsanitary conditions and feeding inadequate amounts of the formulas. The Department is considering steps it can take to encourage more appropriate use of these foods in foreign countries. Furthermore, the World Health Organization (WHO)/UNICEF is working on a code for the marketing of breast milk substitutes. Under current law, FDA has the authority to prohibit the exportation of foods - including infant formulas - produced for domestic consumption and subsequently found to be unsafe. We recommend that the section on exports be deleted from the bill.

RECALL AUTHORITY

In addition to S. 2490 your Subcommittee also has before it H.R. 6940. The Department supports the provisions of H.R. 6940 that would enhance our ability to assure the safety and nutritional quality of infant formulas. However, we strongly oppose the recall provisions proposed by H.R. 6940 because they could significantly discourage recall by manufacturers.

The bill, as passed by the House, provides the Secretary with the authority to prescribe the requirements for voluntary recalls initiated by a manufacturer. Once the manufacturer opts to recall a defective infant formula product it must comply with regulations promulgated by the Secretary defining the scope and extent of recalls. A manufacturer's failure to comply with the recall, would constitute a prohibited act under the Federal Food, Drug and Cosmetic Act.

We agree that the Secretary should be provided the discretionary authority to prescribe by regulations the scope and extent of recalls to assure that defective products are effectively removed from commercial distribution. However, we do not believe that the recall provision in H.R. 6940 would effectively protect the public from adulterated or misbranded infant formulas which have been distributed to the marketplace. On the contrary, we are seriously concerned that this recall provision would be a significant disincentive to manufacturer's recalls of defective products.

The recall system proposed in the bill would penalize responsible and reward irresponsible firms. If a firm voluntarily recalled its infant formula, it would be bound by the Department's recall procedures. If

the recalling firm failed to meet all the requirements of the regulations, it would violate the Act and be subjected to potential additional penalties. A firm which did not even attempt a recall would run no similar risk. We therefore believe that this provision could pose a public health hazard by discouraging recalls by manufacturers.

While we also have other objections to this provision we have taken this opportunity to bring our main concern to your attention. We urge you not to adopt a similar recall provision in any bill that the Subcommittee may report out.

The Department has sent a report on H.R. 6940 to the Chairman of the Senate Labor and Human Resources Committee. I would like to submit a copy of that report for the record.

SUMMARY

Mr. Chairman, we believe that we have taken appropriate administrative steps to ensure, to the extent that our current regulatory authority permits, that problems with infant formulas, similar to the Syntex affair, will not recur. Some of the additional regulatory controls proposed by the pending legislation would be helpful but we are mindful that increased regulation means increased delays and increased costs, both of which this Administration and our Agency are determined to minimize wherever possible.

As a matter of policy:

-- We support the concept of standardized infant formulas for normal babies set out in regulations rather than by statute. The distinction is important since new information will likely lead to changes in nutrient composition. Such changes will be facilitated by regulation.

-- We do not believe premarket testing and approval are needed because such requirements will impose a heavy economic burden on the manufacturers while doing nothing to assure that incidents like the Neo-Mull-Soy chloride deficiency will not occur. We, of course, strongly support appropriate quality assurance and quality control procedures.

-- We do not believe that providing FDA with mandatory recall authority is the key to addressing the basic defects in the ability of either Government or processors to remove such products from the marketplace. It is far more important to provide for improved recordkeeping by firms, inspection authority of those records by FDA, product coding by manufacturers, and plans to implement recalls, than to have mandatory recall authority. Authority to require quality control and assurance procedures in conjunction with record inspection authority would also minimize the occurrence of incidents similar to the recent chloride-deficient infant formula episode.

In conclusion, Mr. Chairman, we are keenly aware of the important responsibilities we have to assure that high standards of quality and safety are maintained for all foods, especially infant formula. My colleagues and I at FDA would welcome the opportunity to assist you and the members of the Subcommittee to modify S. 2490 to reflect the views presented here and to lend our experience and expertise to the consideration of any additional points or issues on infant formula that may be of mutual interest.

Dr. GOYAN. I would like to speak on exports next.

The basic problems in developing countries are preparation of infant formulas under unsanitary conditions and feeding children diluted formulas.

The Department is considering steps it can take to encourage more appropriate use of these foods in foreign countries. Furthermore, the World Health Organization, WHO/UNICEF is working on a code for the marketing of breast milk substitutes. Under current law, FDA has the authority to prohibit the exportation of foods, including infant formulas, produced for domestic consumption and subsequently found to be unsafe. We recommend that the section on exports be deleted from the bill.

In addition to S. 2490, your subcommittee also has before it H.R. 6940. The Department supports the provisions of H.R. 6940 that would enhance our ability to assure the safety and nutritional quality of infant formulas. However, we strongly oppose the recall provisions proposed by H.R. 6940, because they could significantly discourage recall by manufacturers.

H.R. 6940 provides the Secretary with the authority to prescribe the requirements for voluntary recalls initiated by a manufacturer. Once the manufacturer opts to recall a defective infant formula product, it must comply with regulations promulgated by the Secretary defining the scope and extent of recalls. A manufacturer's failure to comply with the recall would constitute a prohibited act under the Federal Food, Drug and Cosmetic Act.

We agree that the Secretary should be provided the discretionary authority to prescribe by regulation the scope and extent of recalls to assure that defective products are effectively removed from commercial distribution. However, we do not believe that the recall provision in H.R. 6940 would effectively protect the public from adulterated or misbranded infant formulas which have been distributed to the marketplace. On the contrary, we are seriously concerned that this recall provision would be a significant disincentive to manufacturers' recalls of defective products.

The recall system proposed in the bill would penalize responsible and reward irresponsible firms. If a firm voluntarily recalled its infant formula, it would be bound by the Department's recall procedures. If the recalling firm failed to meet all the requirements of the regulations, it would be in violation of the act and be subjected to potential additional penalties. A firm which did not even attempt to recall would run no similar risk. We therefore believe that this provision could pose a public health hazard by discouraging recalls by manufacturers.

While we also have other objections to this provision, we have taken this opportunity to bring our main concern to your attention. We urge you not to adopt a similar recall provision in any bill that the subcommittee may report out.

The Department has sent a report on H.R. 6940 to the chairman of the Senate Labor and Human Resources Committee. I would like to submit a copy of that report for the record.

[The following was received for the record:]

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable Harrison A. Williams, Jr.
Chairman, Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510

JUN 3 1980

Dear Mr. Chairman:

There is pending before your Committee H.R. 6940, a bill "To amend the Federal Food, Drug, and Cosmetic Act to strengthen the authority under that Act to assure the safety and nutrition of infant formulas." I take this oportunity to inform you of the Administration's views on this bill.

In summary, the Department supports enactment of the bill, provided that the recall proposals are either deleted or modified in accordance with the recommendations made in this report.

H.R. 6940 would amend the Federal Food, Drug, and Cosmetic Act ("the Act") to prescribe the nutrient content of infant formulas. All infant formulas would be required to provide specified minimum amounts of listed nutrients. In addition, the bill would set maximum levels for protein, fat, caloric content, vitamins A and D, sodium, potassium and chloride.

The Secretary could by regulation revise the statutory specifications and establish requirements for quality factors of nutrients. The Secretary could also establish such quality control procedures as necessary to assure that an infant formula provides nutrients in accordance with this bill. The Secretary could exempt from these nutrient requirements infant formulas specially formulated for infants with metabolic or other health problems.

Each manufacturer of infant formula would be required to submit to the Secretary, after any change in formulation or processing, reports or test results demonstrating compliance with the requirements of the bill. Test results or reports would also be required on each new infant formula. A processor would be required to notify the Secretary of information indicating that an infant formula might be adulterated or misbranded.

Department employees making inspections for the purpose of enforcing the requirements of the bill would have access to and authority to copy and verify any records relating to the distribution of infant formulas.

The Department supports all provisions of the bill described above, which would greatly enhance our ability to assure the safety and nutrition of infant formulas. We believe that it is important that the Secretary have authority to revise the specifications for nutrients and nutrient levels in infant formula, and we therefore commend the provision of the bill that would authorize the Secretary to do so by regulation. We support the provision that would exempt from the statutory requirements infant formulas specially formulated for infants with metabolic or other health problems requiring specialized diets, and would allow the Secretary to prescribe by regulation the use of alternative standards for such formulas. We also strongly support legislative authority to establish requirements for quality factors for nutrients in infant formula. Since infant formulas can be the sole source of nutrition for many infants, it is essential that infant formula contain adequate amounts of essential nutrients and that the infant be able to utilize these nutrients.

We strongly support the provisions of the bill requiring processors of infant formula to notify the Secretary of information indicating possible adulteration or misbranding. This provision would enable the Department to take appropriate and expeditious action.

The provisions of the bill that would provide authority to require processors to make and retain distribution records, and would permit the Department to examine and copy these records, would greatly facilitate the implementing and monitoring of recalls. The authority provided by the bill to require control and assurance procedures and to inspect manufacturers' records would also help to prevent the occurrence of other incidents like the recent distribution of infant formulas deficient in chloride.

However, we strongly oppose the recall provisions proposed by the bill. The bill would authorize the Secretary to prescribe the requirements for voluntary recalls initiated by a manufacturer. Once the manufacturer voluntarily initiated recall of a defective infant formula product, it would be required to comply with regulations promulgated by the Secretary defining the scope and extent of recalls. A manufacturer's failure to comply with the recall regulations would constitute a prohibited act under the Act. The Secretary would be required to review the voluntary recall by the 15th day and at least every 15 days thereafter until the recall was terminated. The manufacturer would be required to report recall actions to the Secretary by the 14th day of the recall and at least every 14 days thereafter until the recall was terminated.

We agree that the Secretary should be provided the discretionary authority to prescribe by regulations the scope and

extent of recalls to assure that defective products are effectively removed from commercial distribution. However, we do not believe that the recall provision in H.R. 6940 would effectively protect the public from adulterated or misbranded infant formulas which have been distributed to the marketplace. On the contrary, we are seriously concerned that this recall provision would be a significant disincentive to manufacturers' recalls of defective products.

The recall system proposed in the bill would penalize responsible and reward irresponsible firms. If a firm voluntarily recalled its infant formula, it would be bound by the Department's recall procedures. If the recalling firm failed to meet all the requirements of the regulations, it would violate the Act and be subjected to potential additional penalties under the Act. A firm which did not even attempt a recall would run no similar risk. We therefore believe that this provision could pose a public health hazard by discouraging recalls by manufacturers.

Furthermore, since there is no explicit statutory authority for the Department to obtain an order for mandatory recall, providing explicit authority only to monitor voluntary recalls might lead a court erroneously to conclude that this was the exclusive remedy available to the Department.

We would therefore urge that the voluntary recall provisions be deleted from the bill.

In the alternative, we would not object if the bill were amended to substitute for the present recall provisions a clarifying amendment to the Act which would make explicit the authority of the courts to mandate product recalls by manufacturers, and to authorize the Department both to determine the scope and extent of the recall and to monitor its effectiveness, as a part of the injunctive relief available under section 302 of the Act. Such a provision would resolve the uncertainty as to the Department's authority to obtain such judicial relief, a question on which there is currently a split of authority in the courts.

In addition, the provisions of the bill establishing detailed timetables for monitoring of recalls are unnecessary. Such specific provisions would prevent the Department from exercising judgment as to the extent and frequency of monitoring by the Department and reporting by the manufacturer. Rather, we would prefer to design appropriate recall procedures for each particular recall situation. The Department has recently clarified its recall procedures and developed and implemented, with industry cooperation, detailed guidelines for the removal of violative products from the marketplace. We believe that it would be inappropriate to apply different and less flexible procedural requirements to voluntary recalls, as H.R. 6940 would do.

We would also note that the most serious defect of current law, which hampers the ability of manufacturers and the government to remove defective products from the market, is not the absence of adequate procedures for conduct and monitoring of recalls, but rather the lack of controls permitting tracing of products. We note that the provisions of the bill providing authority to require manufacturers to make and retain distribution records would cure this defect.

For the foregoing reasons, we urge that the provisions on voluntary recall be deleted from the bill.

Finally, we recommend two technical corrections to the bill. First, we would suggest that an additional footnote be added to those enumerated under the nutrient table in subsection (g). The new footnote should indicate the necessity of assuring that protein sources in infant formulas are bioequivalent to casein as follows:

> "Casein equivalent. Formulas shall provide per 100 available kilocalories a minimum of 1.8 grams of protein of a biological quality equivalent to that of casein. Proteins with a biological quality less than 100% of casein shall be increased proportionally to a level to compensate for the lower quality provided that no protein with a quality less than 70% of casein will be used."

Second, there is a minor error in the nutrient table in subsection (g) pertaining to the minimum level of essential fatty acids (linoleate). Specifically, the 3.0 percent of calories for linoleate should be changed to 2.7 percent to attain technical accuracy.

In summary, while certain proposals of the bill would strengthen the Department's regulatory authority with respect to infant formula, we believe that specific provisions should be changed as indicated in this report. We therefore recommend that the bill be favorably considered if modified in accordance with our recommendations.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely yours,

/s/ Patricia Roberts Harris

Patricia Roberts Harris

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Dr. GOYAN. Mr. Chairman, we believe that we have taken appropriate steps to insure, to the extent that our current regulatory authority permits, that problems with infant formulas, similar to the Syntex affair, will not recur. Some of the additional regulatory controls proposed by the pending legislation would be helpful but we are mindful that increased regulation means increased delays and increased costs, both of which this administration and our agency are determined to minimize wherever possible.

As a matter of policy we:

Support the concept of standardized infant formulas for normal babies set out in regulations rather than by statute. The distinction is important, since new information will likely lead to changes in nutrient composition. Such changes will be facilitated by regulation.

We do not believe premarket testing and approval are needed because such requirements will impose a heavy economic burden on the manufacturers while doing nothing to assure that incidents like the Neo-Mull-Soy chloride deficiency will not occur. We, of course, strongly support appropriate quality assurance and quality control procedures.

We do not believe that providing FDA with mandatory recall authority is the key to addressing the basic defects in the ability of either Government or processors to remove such products from the marketplace. It is far more important to provide for improved recordkeeping by firms, inspection authority of those records by FDA, product coding by manufacturers, and plans to implement recalls, than to have mandatory recall authority. Authority to require quality control and assurance procedures in conjunction with record inspection authority would also minimize the occurrence of incidents similar to the recent chloride-deficient infant formula episode.

In conclusion, Mr. Chairman, we are keenly aware of the important responsibilities we have to assure that high standards of quality and safety are maintained for all foods, especially infant formula.

My colleagues and I at FDA would welcome the opportunity to assist you and the members of the subcommittee to modify S. 2490 to reflect the views presented here and to lend our experience and expertise to the consideration of any additional points or issues on infant formula that may be of mutual interest.

Thank you.

Senator METZENBAUM. Thank you, Dr. Goyan.

I see the baby is crying. We did not have any crying when we had the earlier testimony. Maybe the baby understands some of your positions may not be in his or her best interests, maybe not.

Both FDA and the consumer parents have testified that they would like to see nutrient requirements in regulations rather than legislation. Later today, the Infant Formula Council and the American Academy of Pediatrics will support this as well. Yet, the two spokesmen for consumer's health, claim that waiting for the FDA to put these requirements into regulation will delay effective date of the regulations.

When do you expect that FDA will have regulations regarding nutrient content?

Dr. GOYAN. Let's go over that just a little bit.

The points that Mr. Pilot made were essentially correct. We have guidelines in place now recommending the 1976 AAP guidelines for nutritional content.

Senator SCHWEIKER. Are they in effect now?

Dr. GOYAN. They are guidelines, not regulations.

Senator SCHWEIKER. When will they be in effect?

Dr. GOYAN. What we are planning on doing is continuing to look at the results of the conference we held with regard to nutritional content and come up with final regulations within the next year.

However, I would like to point out that, to the best of our knowledge, all of the infant formula makers at the present time use 1976 guidelines.

Incidentally, I would also like to make clear that FDA has no objection to your writing into law the 1976 guidelines, as long as we can change them by regulation in the future.

Senator SCHWEIKER. You have no objection?

Dr. GOYAN. None at all.

Senator METZENBAUM. Is the language as contained in the House bill acceptable to you?

Dr. GOYAN. That is acceptable.

Senator SCHWEIKER. Are you sure that is correct? I looked at the table in the House bill closely, and I don't see any maximum limit on iodine. I believe the Academy of Pediatrics has set a maximum for iodine, like the limit the house bill places on vitamins A and D, since iodine can be toxic, too——

Dr. GOYAN. That may be so. We would be happy to work it out so it is exactly the same. We have no objection to that.

Senator SCHWEIKER. Dr. Goyan, how can we avoid the situation whereby the 1976 scientific recommendations, as proposed by pediatricians, did not get promulgated by you until this year? How do we avoid that kind of delay again? As I understand it, the actual formula that caused this trouble was in accordance with FDA regulations on nutrient content at the time.

Dr. GOYAN. In accordance with 1971, but not 1976. You are correct.

It was our understanding at that time that all of the infant formula manufacturers were following the 1976 guidelines. What had happened was this, we had the 1971 list in place by regulation, and we worked with the American Academy of Pediatrics in establishing the 1976 guidelines as well as people from the industry, but we had not put them into place as regulations because we were waiting for the conclusion of some international discussions taking place with regard to infant formulas. We thought we would wait until we had final guidelines that came out of that, in the belief that all companies were following the 1976 guidelines.

Anyway, we did not feel it was necessary.

Senator SCHWEIKER. One of the principal manufacturers has obviously not, following the 1976 guidelines.

Dr. GOYAN. The point is, the company felt they were following the 1976 guidelines. They believed they were following 1976 guidelines. It was a quality-control breakdown. This is why we feel so strongly about the importance of quality control.

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Senator SCHWEIKER. They believed they had the chloride in the formula, you are telling us?

Dr. GOYAN. Yes.

Senator SCHWEIKER. I come back to my original question:

How can we eliminate the 4-year delay from the time the academy's recommendations are promulgated until FDA puts them into effect? You are telling us this morning that it's going to be another year from now before we get final regulations. I am really disturbed about that time lag.

You answered Chairman Metzenbaum's question by saying it still is going to be another year, possibly. I do not comprehend that.

Dr. GOYAN. I think that is one of the reasons I strongly support the idea of your writing in the law the present 1976 guidelines; because we have to go through notice and comment, rulemaking, which takes time——

Senator SCHWEIKER. I understand that. But I have got to believe there has to be some shortcut procedure when children's lives are at stake. Surely we can come up with something within the bureaucracy to solve a problem like this.

Dr. GOYAN. You are talking about in the future. We certainly will.

Senator SCHWEIKER. I am talking about manufacturers following regulations and FDA not even having regulations that are current. You said, you hoped to act within a year; I believe your testimony said August, or whenever. We are 4 years late already. I just do not want to see this tragic situation repeated again, because of some procedural requirements.

It seems to me if you do not have authority to act more quickly, tell us that, and we will give it to you. If you do have authority to do it, let's do it. But this idea of waiting another year before we have final regulations on something that obviously is affecting a lot of children's lives—I get a little excited about that.

Dr. GOYAN. We can certainly move the regulations more rapidly——

Senator SCHWEIKER. Do you need more authority to do this, or is there a bureaucracy problem?

Dr. GOYAN. We have to go through notice and comment rulemaking in order to do this. We believe that all of the infant formula manufacturers are presently following the 1976——

Senator SCHWEIKER. You believed that before. That is what got us into trouble. You believed that before.

Senator METZENBAUM. Have you done any checking?

Dr. GOYAN. We have checked all infant formulas on the market, yes, and they are all following 1976——

Senator SCHWEIKER. You have checked them. Did you not just tell me a minute ago it was not the fact they ignored chloride; it was the fact that the manufacturing process broke down?

Dr. GOYAN. The quality-control process broke down.

Senator SCHWEIKER. How do you know the manufacturing process is not going to break down again?

Dr. GOYAN. There is no way of knowing that. That is one reason we want these quality-control procedures in law, and we want to have inspection authority so we can make sure they are in place.

Senator METZENBAUM. What type of quality-control regulations do you plan to develop?

Dr. GOYAN. I did not hear you.

Senator METZENBAUM. What types of quality-control regulations do you plan to develop, and how long will they take?

Dr. GOYAN. They are presently in process. We should have them ready for publication by December of this year.

Senator METZENBAUM. December?

Dr. GOYAN. At the latest.

Senator METZENBAUM. How long after that will it take to put them into effect?

Dr. GOYAN. How long will notice and comment take, roughly?

Ms. BUC. Sixty days of comment and some additional time to process them, and then whatever time is necessary to phase them in with an effective date. I would estimate that under the circumstances, since this is, as you all recognize, an important area, that the attention in the bureaucracy to this is going to be a very high priority, and that we ought to be able to get them out promptly after their first proposal in the Federal Register.

Senator METZENBAUM. What would you estimate to be that period?

Dr. GOYAN. Six months at the outside.

Senator METZENBAUM. Now, we are talking about July of 1981?

Dr. GOYAN. Correct.

Senator METZENBAUM. If there is an objection or challenge to those quality-control regulations, how much additional delay would there be?

Ms. BUC. I would hope none with the procedure that is contemplated in the House bill and also we hope in the Senate version. We are talking about notice and comment rulemaking, that is all. So that our final rule is final. That is, there should not be any further hearings before FDA. We would oppose a stay in the Federal courts, but of course we cannot control what a district court might do to our regulations.

Senator METZENBAUM. Why is it that you cannot get those regulations out until December? I must confess that one of the problems I have with government is the fact that it always takes so much longer to do that which private industry or a private individual could get done. If I were a practicing lawyer or if I were heading a company, I would say: I want the regs completed and I want it done by June 10 or July 15, whatever the date is. Government never seems to operate that way.

Dr. GOYAN. Remember that up until the time that this bill has been put forward, we have not had authority to require this. Thus, we are moving forward on the basis that we believe that these bills will be passed; we will then have authority, and then we can require it. It is complex because we have to consider all things that might go wrong. I have to caution you that none of us would have anticipated the sort of problem that came up with chloride. I do not think anyone realized that such a thing could happen. Therefore it is important that we try and anticipate all the things possible.

Senator METZENBAUM. Dr. Goyan, you sharply challenged the House language with respect to recall.

Dr. GOYAN. Correct.

Senator METZENBAUM. And said you felt it would be an impediment rather than an advantage, step forward.

What do you think should be done with respect to total recall?

Dr. GOYAN. We would prefer to see it come under injunction authority so we could go to court and say, we want to make this recall and have them order it.

Senator METZENBAUM. Do you have such authority in any field at the present time?

Ms. BUC. Specifically, no. We have sought it under our general injunction authority in two cases. We have won one and we have lost one. We also have statutory authority under the medical device amendments to order recalls, but through a more cumbersome procedure.

Senator METZENBAUM. You would like injunctive rights to be given to you?

Ms. BUC. We would like the statute to make it clear that courts have authority to order recalls as part of their general injunctive authority.

Senator METZENBAUM. You have taken issue with the export provision of the legislation.

At the hearing last fall, when asked what Syntex intended to do with the remaining unsafe formula, the company replied it was considering sending it overseas. I do not have to tell you that I think that was crass, indifferent, irresponsible. If it is not good enough in this country, how do you send it overseas? Since that formula had originally been entered into interstate commerce, under the current law, it could not be exported.

However, if it had been manufactured just for export and lacked essential nutrient chlorides, the formula could have been sent to a developing country.

Under those circumstances, it is obvious that that was a potentially dangerous and irresponsible kind of development. We can do something to other nation's children that we are not permitted to do to our children.

Now, you say you do not want export provisions. You tell us about the World Health Organization. But what could you have done if they had only manufactured the product and said they were going to use it for export? You had no authority.

Dr. GOYAN. You are correct, Senator. However, I would like to say that I do not believe any company would deliberately export something they think would make children sick.

Senator METZENBAUM. They said they were going to donate it to an organization in order to be sent overseas.

Dr. GOYAN. The Neo-Mull-Soy had been used when supplemented with sodium chloride, in which case it should have been safe. I expect that is what they were thinking of doing.

Senator METZENBAUM. Dr. Goyan, you are missing the point. If you cannot sell it in this country, it should not be permitted to be exported overseas. You do not have that authority at the present time, if the product is manufactured only for export, and yet you are sitting here and telling us you do not think that ought to be in the legislation. I do not understand that.

Dr. GOYAN. Senator, a task force under Esther Peterson in the administration is looking at the whole issue of exports. As soon as that is completed, we will have a position.

Senator METZENBAUM. That is not an adequate answer. Every time government has something to do, they have a task force. I conducted a hearing 2 or 3 days ago about difficulties with respect to radiation exposure. The task force was headed up by an individual in the Government who was not objective at all; who was really on the opposite side of the people who were affected. I do not think it is adequate to say a task force. That is the dodge that Government has.

Government says, we will appoint a committee to study it. Any time there is a committee appointed to study something or a task force, it means somebody does not want to bite the bullet.

What I am saying is, I do not understand FDA being here and opposing the export provision for some reasons that I have difficulty understanding, such as the World Health Organization is going to do something about it; such as a task force is studying it. If it is wrong, it is wrong. We ought to ban it. If it is not good enough for our kids, it is not good enough for the kids of some people in far-off lands.

I just think your position ought to be reevaluated. If you do not like the specific issue, well enough, but absent that, I think you owe it to the Congress to reevaluate that position and give us at least a better answer or else change your position.

Have you conducted any animal studies to document what ill effects are caused by chloride deficiency and what long-term effects may occur?

Dr. GOYAN. We are looking at the possibility that some of our guinea pigs that we keep out in the Beltsville area might be a good model for this particular problem. I do not know if there is any animal model available at the present time. We hope this will work out to be one.

Senator METZENBAUM. You started some tests last Monday in this area?

Dr. GOYAN. I do not know—yes, we did.

Senator METZENBAUM. Rather late to just be starting last Monday, in view of the problem with respect to the chloride deficiencies, I would say.

Dr. GOYAN. We have also worked, of course, with NIH and CDC with regard to this.

Senator METZENBAUM. I have no further questions.

Senator SCHWEIKER. I have a question.

Coming back to the regulations, I am still troubled that here it is June and we are talking December before the regulations are in place. That just bothers me.

Do we not have some provisions of the law, even with the Administrative Procedures Act, some kind of serious risk or imminent danger, or imminent hazard provision that gives you a way to shortcut this process? Why are we not using it? I have trouble comprehending this point.

Dr. GOYAN. It is not just a matter of writing regulations; it is also deciding exactly what we need to do in terms of each of the

steps in order to assure it does not happen again, what the quality-control steps should be.

Senator SCHWEIKER. It certainly is not a matter of doing it. We have had the wrong regulations. The wrong regulations are still in place. We hear the personal stories of the witnesses here this morning, and I cannot comprehend that we would not make some effort to put the right regulations out, without delay.

Do you have the authority you need to do that or not?

Ms. BUC. We have the authority to issue regulations which prescribe what should be on the labels of these products. That is the authority that we used to incorporate the 1971 AAP guidelines.

As you infer, we could have used that authority, that same authority, to put out the 1976 AAP guidelines as mandatory FDA regulations. In part, the reason we have not done so, following the problem with Neo-Mull-Soy, is the expectation that the bill—that you have under consideration would pass, that the job would be done, and that the fact is that the Congress does not need notice and comment rulemaking.

The answer to your other question, though, is, yes, there are provisions for emergency procedures under the AAP. The difficulty here is that the quality-control regulations, which are the ones that I think everyone expects would genuinely have prevented the Neo-Mull-Soy situation, or at least we all hope so, are precisely those for which we do not have any authority to promulgate under the present law. That is why we are here. We are asking for that authority. We expect to have those regulations ready to promulgate virtually immediately after the legislation is passed giving us the authority to do it. We have anticipated the passage of the statute and hope to be ready to go very soon.

Senator SCHWEIKER. Well, I can understand your second point about the quality-control regulations; and I acknowledge that that is a different situation, one that I am sure is subject to a lot of litigation and possibly some obvious disagreement. But I really hope, Dr. Goyan, that you will look at some of your regulatory procedures and put some kind of fast track device in here for the future, when we're dealing with things that affect the health and safety of people. I hope we will not just go on doing business as usual when we have cases like this. It took something like 11 years to establish a peanut butter regulation. Now fortunately nobody dies from peanut butter, and this was before Jimmy Carter was President; so he probably didn't care. But the point is, 11 years for peanut butter is sort of par for the course. Fortunately, the peanut butter case didn't pose any serious health risks. But we cannot approach serious problems on that peanut butter level. We need a fast track system.

I realize that the infant formula problem before us today is rather unique, but I have got to believe that we ought to have a fast-track procedure to deal with this kind of thing, Dr. Goyan.

Senator METZENBAUM. Thank you very much, Dr. Goyan, and we appreciate your being here with your legal counsel, and look forward to working with you to move this legislation very rapidly through the Senate.

In connection with certain aspects of it, we do have some disagreement, but we would like to try to work it out with you so that

you will see things our way. If not, we will be glad to work it out with you on a mutually agreeable basis.

Dr. GOYAN. Thank you very much, Mr. Chairman. We really appreciate your help in this regard. We feel very strongly we need this legislation.

Senator METZENBAUM. Thank you, Doctor.

Our next witness is Mr. Robert C. Gelardi, of the Infant Formula Council which, it is my understanding, is the trade association representing the five companies most active in this field.

Mr. Gelardi, we are happy to have you with us this morning and happy to have you introduce your associates, and also would ask you if you could summarize your statement rather than read it in its entirety.

STATEMENT OF ROBERT C. GELARDI, EXECUTIVE DIRECTOR, INFANT FORMULA COUNCIL; ACCOMPANIED BY RICHARD H. TENNYSON, PH. D., VICE PRESIDENT, QUALITY ASSURANCE, MEAD-JOHNSON & CO.; RICHARD WOOD, COUNSEL; AND DR. HENRY SAULS, VICE PRESIDENT FOR MEDICAL AFFAIRS, ROSS LABORATORIES

Mr. GELARDI. I will be glad to do that, Mr. Chairman.

On my right is Dr. Tennyson, who is vice president and responsible for quality control, research, and development, with the Mead-Johnson & Co. On my immediate left is Richard Wood, counsel to the Infant Formula Council. On his left is Dr. Henry Sauls, vice president, medical affairs, with Ross Laboratories.

We appreciate the opportunity to appear today on behalf of the Infant Formula Council. The infant formula industry is acutely aware of its responsibility with respect to infant nutrition and health. We, thus, concur with the intent of legislation to foster infant health by assuring the appropriate nutritional content of infant formulas.

The members of the Infant Formula Council recognize that infant formulas are often the sole source of nutrition for infants, and that design, manufacture, and control of infant formulas, therefore, require special care.

This special care has been exercised for a long period of time and has resulted in a remarkable record of consistent high quality products over the years. Further recognizing the importance of human milk and breastfeeding, the industry fully acknowledges breastfeeding as the preferred mode of feeding and constantly works to improve its formulas to incorporate as much as possible the nutritional benefits provided by human milk.

We also recognize that following a major recall last year of one manufacturer's infant formula, questions were raised concerning how best to assure that those who rely on infant formula can remain confident that formula meets the nutritional needs of infants.

The industry supports the efforts of the Food and Drug Administration, through its public hearing process, to thoroughly examine this question, and recognizes the need for appropriate regulatory policy with respect to infant formula.

The Infant Formula Council participated in both a public meeting on quality assurance and quality control procedures, and a

public hearing on nutrient content of infant formulas, held earlier this year by the Food and Drug Administration. With the chairman's permission, we would like to submit the text of our presentations for inclusion in the record of these proceedings.

Senator METZENBAUM. Without objection, so ordered.

[The following was received for the record:]

QUALITY CONTROL OF INFANT FORMULAS

A statement submitted to the
Food and Drug Administration
by the
Infant Formula Council

February 19, 1980

Speaker
Richard H. Tennyson, Ph.D.
Vice President Quality Assurance
Mead Johnson & Company

I. Introduction

On behalf of the Infant Formula Council, which represents manufacturers of infant formula in the United States, I am pleased to share with you the following industry information regarding manufacture and quality control in infant formulas. Dr. Henry Sauls also will provide industry information; his presentation will focus on the development of infant formulas and their clinical testing.

In the manufacture of complex products, such as infant formulas, it has long been recognized that consistent success can only be achieved through constant diligence and attention to essential detail. First, facilities must be designed, constructed, and maintained to allow an orderly flow of materials, and to make it easy to keep the plant properly clean. Second, production and control systems must be carefully detailed. Third, personnel must be carefully trained in use of these systems. As technology develops and experience accumulates, facilities and systems must be continually updated and personnel must be retrained. The infant formula industry, as it has developed since the early years of this century, has paid special attention to these important factors.

In recent years, many of these factors have been written down by the Food and Drug Administration as Current Good Manufacturing Practice (CGMP) regulations. Proposed in-depth revisions of GMP's for Manufacturing, Processing, Packing or Holding Human Food were published by the Food and Drug Administration on June 8, 1979; we believe it is significant that the Infant Formula Council has endorsed this proposal without adverse or modifying comment. Indeed, systems in use in the infant formula industry are such that members of the Infant Formula Council are committed to practices beyond those of the proposed general food GMP's with respect to raw material control, checking of product composition, plant cleanliness, and preparation and maintenance of detailed records.

Liquid infant formulas are classified as low-acid foods. The members of the Infant Formula Council are therefore also fully committed to the letter and spirit of the CGMP for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers as most recently revised (March 16, 1979). These regulations require that the essential details of the sterilization process be registered with the FDA. It is required that records of the heat processing of each product batch be maintained and be available to FDA personnel on request. Further, any changes in the sterilization process must be validated and filed with the FDA.

The industry's commitment to these practices is detailed in a document which was provided to FDA earlier, and which we would like to submit again at this meeting. Our continuing commitment to high-quality products is evidenced by a series of actions which I would like to discuss with you.

"Quality" when applied to infant formulas refers to all the properties which result in sound nutrition, microbiological safety, physical elegance, and convenience in use. Furthermore, it is important to remember that "quality" (like "good manufacturing practice" as discussed above) is a relative term whose meaning is constantly changing because standards become more exacting as knowledge advances; the high-quality product of 1960 might not be viewed the same in 1980.

II. Development of the Product

Quality can be achieved only if it is carefully designed and built into the product. Accordingly, the best current knowledge of infant nutrition, as available from experts in nutritional science and pediatric care, is used in the development of infant formula products. Assembly of an appropriate formula is an exacting task; it requires careful selection of raw materials and development of methods for processing these materials into a product of the desired elegance. Considerable analytical work is done to assure that the selected combination of process and materials achieves the desired nutrient composition. As appropriate, the product may then undergo additional testing as Dr. Sauls will discuss later.

III. Initial Quality Control Program

These preliminary testing periods during the design and development of infant formula are used to learn a great deal about the critical processes and properties of the product and the critical properties of the ingredients used. From this knowledge and application of current principles of quality assurance, an initial program of in-process and laboratory controls is defined to assure the process is effective and the product meets the high quality expected in an infant formula.

This initial control program is an intensive effort to assure that all lots are acceptable and to learn as much as possible about the product and the system by which it is produced. If this stage reveals opportunities for further improvement of the product, the composition or process may be adjusted

while the intensive initial control program continues. If the intensive initial control program shows that the process is operating properly to yield a product having the desired quality, the control program is adjusted to concentrate on the critical control points.

IV. The resulting normal manufacturing and control sequence is as follows:

A. Raw Materials

Analytical data for all incoming raw materials are evaluated to assure that they meet carefully defined standards of quality prior to use. Where applicable, the standards of quality defined by the Food Chemicals Codex, U.S. Pharmacopeia, National Formulary, or other official references are used, always with emphasis on any properties defined as critical during product development activities. Each infant formula manufacturer maintains and constantly updates its own list of approved vendors for each raw material, and each new vendor is carefully evaluated and qualified before being added to the list of approved sources for the item.

B. Major Ingredients

In manufacturing the product, the major ingredients (protein sources, fats, and carbohydrates) are added directly in the processing of each batch. Each lot is analyzed to verify the presence of the proper quantities of protein and fat. This is usually done as an in-process control analysis to allow fine-tuning the batch composition, but it may also be done as part of the final control analysis of the finished batch. Direct analysis for total carbohydrate is usually impractical so carbohydrate is determined indirectly. The total quantity of solids is measured, and carbohydrate is calculated as the mathematical difference between the total solids and the sum of protein, fat, and ash.

C. Other Ingredients

Ingredients such as vitamins and certain minerals may be added individually to the batch. Alternatively, they may be added as premixes. Such premixes are prepared in bulk and analyzed for proper concentration and uniformity of mixing of each of the nutrients in the premix. Presence of the proper quantity of the premix can be checked by analyzing the batch for one or more of the ingredients in the premix. This may be done during processing, or as a final control procedure, or both. Irrespective of the manner of

addition of these ingredients, appropriate in-process or final control measures are completed to assure that proper additions have been made.

D. Canning and Sterilization

Along with the product development activities, heat processing techniques are developed to allow the products to be sterilized properly. The processes are specified in standard manufacturing instructions and carried out under the direction of plant personnel thoroughly trained in the Low-Acid Food regulations. Prior to release of the batch, the batch record is checked to verify that the sterilization has been done according to the established procedure.

Sterilization as described above destroys bacteria in the canned product and allows it to be handled safely like other canned foods. Additionally, the manufacturing process includes use of inspection devices to remove any containers which might leak and introduce bacteria into the formula after heat processing. To assure that these additional measures have been effective, samples from the finished batch are subjected to detailed inspection to assure freedom from contamination.

V. Additional Considerations

Further, specifications and controls are established for other process materials which might directly affect product quality. These procedures assure that compressed air or nitrogen, cooler water, steam, and ingredient water are suitable for their intended purposes. Similarly, materials and methods for cleaning equipment are carefully selected to assure proper sanitary control while avoiding product contamination.

Beyond the regular surveillance described above, members of the Infant Formula Council require additional measures to provide continuing assurance that the desired quality is consistently achieved.

Periodically, samples of selected batches are taken for a detailed analysis. This provides continuing assurance that there are no undetected changes in processing, equipment, or material quality which might adversely affect the quality of the product. The detailed analyses assure that the system is functioning as intended, and that no unexpected loss of nutrients is occurring during processing.

During the product development period, the product is studied to determine

the period of time that the product retains the nutrient composition and physical elegance required in an infant formula. This study establishes the date which is stamped on each container of infant formula to inform the consumer of the time beyond which use of that can of product is not recommended. Such open dating of infant formula products has been used by all of the members of the Infant Formula Council for all infant formulas for over seven years. Each formula bears language clearly understandable to consumers, that is, "Use By" or, "Use Before" and the date. To monitor the continued appropriateness of the date designated, periodic product samples are stored for detailed analysis and physical evaluation at selected intervals after the date of production.

When contaminants of concern are identified in the environment, raw materials and/or products are surveyed for the presence of these contaminants. These surveys are repeated periodically or, if necessary, maintained as regular practice. Most potential contaminants are soluble in, and migrate into, fats and oils. In the manufacture of most formula products, the fat from the milk or other protein source is removed, thus removing fat-soluble contaminants along with the fat. The fat is then replaced with highly refined edible oil; accordingly, fat-soluble contaminants from the environment have not been detected at significant levels in formula products.

For those potential contaminants which are not fat-soluble, regular surveillance is maintained until some means for eliminating the potential for environmental contamination has been shown to be successful. For example, the Infant Formula Council is engaged in a voluntary cooperative testing program for lead in infant formulas. Lead testing results are provided to the FDA under this voluntary cooperative program. As a consequence of this work, the infant formula industry can assure lead levels remain at the lowest levels possible.

The members of the Infant Formula Council always have been fully aware that infant formulas are often the sole source of nutrition for infants, and that design, manufacture,and control of infant formulas therefore requires special care. This special care has been exercised for a long period of time

and has resulted in a remarkable record of consistent high-quality products over the years. The systems described above represent the progress to this date from use of this operating philosophy and our commitment to exert continued vigilance in the future. We are confident that such a course will result in further progress toward even higher quality products in future years.

INFANT FORMULA COUNCIL

INFANT FORMULA COUNCIL'S

COMMITMENT

TO

GOOD MANUFACTURING PRACTICES

The Infant Formula Council is a voluntary non-profit trade association composed of five companies engaged in the manufacture and marketing of commercial infant formula. The individual members are Loma Linda Foods, Mead Johnson & Company, Ross Laboratories, Syntex Laboratories and Wyeth Laboratories.

The Council notes that the proposed regulations /"Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Human Food" appearing in the June 8, 1979 Federal Register (43 F.R. 33238) Docket No. 78N-0296/ would apply to the manufacture of all infant formulas by member companies. In addition, all liquid infant formula products, which represent the majority of infant formulas sold in this country today, are required to be manufactured in accordance with 21 CFR 113-Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, to which the Council adheres.

In general, the Infant Formula Council endorses all of the provisions contained in the proposed regulation. We believe that the provisions of this proposal reflect to a great extent the continuing level of care and control exercised by members of the infant formula industry. However, there are a number of additional GMP procedures to which the industry voluntarily subscribes. The specific procedures to which the Infant Formula Council members are already voluntarily committed are as follows.

1. With respect to proper handling of raw materials, members of the Infant Formula Council require that each component shall be evaluated for conformity with appropriate written specifications. In lieu of testing by the manufacturer, a report of the analysis may be accepted from the supplier of a component, provided that one specific identity test is conducted on each component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analysis at appropriate intervals.

2. With respect to the controls exercised over each batch of infant formula product, we require that there shall be appropriate process control or laboratory determination of satisfactory conformance to final specifications for the infant formula.

3. Since infant formulas are manufactured on a batch basis, each member of the Infant Formula Council maintains batch production and control records of sufficient detail and accuracy to determine the history of the components used in a batch, how the components were processed and other controls associated with manufacture and packaging of the batch.

4. Written procedures are established for cleaning and sanitizing of production equipment and areas. For manual cleaning and sanitizing operations a record is maintained and signed or initialled by a responsible person showing the completion of the established cleaning procedures. For systems which are cleaned in place, adequate equipment functionality records are retained.

5. Members of the Infant Formula Council each maintain a current written procedure which is used for infant formula products under their control, including a plan for effecting recalls of any such products. This procedure applies to all infant formula products manufactured by the members and is not limited to those manufactured in accordance with the Low-Acid Food GMP's.

6. While the members of the Infant Formula Council do maintain the records described in the proposed food GMP's, and those referred to above, our record keeping period requirement is more stringent than that proposed. Members of the Infant Formula Council maintain records described in the proposal for a period of at least one year beyond the shelf life of the product. In many instances this is far longer than the two years from the date of manufacture contained in the proposed regulations.

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NUTRIENT COMPOSITION OF INFANT FORMULAS FOR NORMAL, FULL-TERM INFANTS

A statement submitted to the
Food and Drug Administration
by the
Infant Formula Council

March 12, 1980

Speaker
Jerry L. Moore, Ph.D.
Vice President, Research & Development
Mead Johnson Nutritional Division

Introduction/Background

On behalf of the Infant Formula Council, thank you for the opportunity to appear today. Members of our industry are acutely aware of the importance of our products to infant nutrition and health and we welcome the opportunity to participate in these proceedings regarding nutrient composition of infant formula.

Mr. Chairman, members of the Infant Formula Council acknowledge that breast milk is the preferred food for human infants. The industry concurs with and is supportive of efforts that encourage successful breastfeeding. Member companies also recognize that substitutes for breast milk or supplements to breast milk have been sought and used since earliest recorded history. But, only with the advent of sanitary food preservation methods in the late 1800's and the application of clinical nutrition knowledge and technology developed in the 1900's, did satisfactory milk substitutes become possible. Today's commercial infant formulas are sound alternatives to human milk in safely and effectively meeting the normal nutritional requirements of infants. Satisfactory substitutes and supplements for breast milk, therefore, will continue to be needed whenever, in the words of the American Academy of Pediatrics Committee on Nutrition, "breastfeeding is inappropriate, unsuccessful or stopped early." In addition, the need for specialized formulas to meet the dietary needs of infants with a variety of medical conditions may increase as knowledge of clinical nutrition continues to grow.

Summary

Against this background, we are pleased to provide testimony that includes the following key points:

1. Availability of infant formula that complies with satisfactory nutrient standards must continue to be ensured.

2. Improvements in infant formula, based on new medical and scientific information, should be encouraged and regulatory barriers to such product improvements avoided.

3. Revisions in existing regulations (21 CFR 105.65) are appropriate to bring the regulations into accord with current nutritional guidelines developed by appropriate medical and nutritional authorities.

4. Guidelines provided by the Committee on Nutrition of the American Academy of Pediatrics as revised in 1976 and in 1980 constitute an appropriate basis for updating current regulations. Guidelines contained in the

Recommended International Standard for Infant Formula developed by the Codex Alimentarius Commission in 1976 should also be considered. (Exceptions to some of the American Academy of Pediatrics' guideline maxima will be discussed and some areas unaddressed by the document will be considered in the testimony following.)

5. The guidelines of the Committee on Nutrition of the American Academy of Pediatrics apply to formulas for normal, full-term infants. Care must be taken to assure that regulations governing such formulas do not impede the development and availability of formulas for infants with special dietary needs resulting from specific diseases or medical conditions.

6. Establishment and enforcement of any revised regulations dealing with infant formula nutrient composition must recognize the differences among a) scientifically recommended nutrient guidelines; b) nutrient level limits contained in regulations, and c) action levels or limits that constitute grounds for enforcement actions. Nutrient level limits codified into regulations must carefully be established and enforcement should be effected through the tolerance principles utilized in effecting current Good Manufacturing Practices.

Principles/General Recommendations

The levels of nutrients presently found in commercial infant formula and the recommendations and regulations for infant formula composition are based primarily on two sources of information. The first is nutrient analysis of human milk, because milk from healthy, well-fed women is believed to be the best feeding for normal infants. (Yet, it must be emphasized that wide variations in human milk composition do exist. For example, protein content may vary from 7 to 14 g/l; sodium 5 mEq/l to 20 mEq/l; unsaturated fatty acids may vary from 5 to 45% of total fat, depending on the mother's diet. Infants tolerate these wide variations with ease.) The second source of information is controlled clinical research conducted with infants fed human milk and a number of infant formulas of defined nutrient composition.

The recommendations of the Committee on Nutrition of the American Academy of Pediatrics as published in 1976 and modified slightly in their recently revised document are based on a thorough review of available information on the composition of human milk and on basic and clinical nutrition research. These recommendations are very similar to the Recommended International Standard for Infant Formula published by the Codex Alimentarius Commission in 1976. We agree that the recommendations of the Committee on

Nutrition reflect the best nutritional information currently available. We concur with the Committee position on breast-feeding and, with the few exceptions to be discussed below, endorse adoption of its guidelines for the nutrient levels in infant formula.

We specifically acknowledge concurrence with the Committee's recommended minimum and maximum levels for protein in infant formulas. Available data provide sufficient basis for retaining the minimum 1.8 gm/100 Kcal recommended by the Committee on Nutrition in its 1967, 1976, and 1980 statements as well as by the 1976 Codex Alimentarius Commission standard. Such a minimum will ensure that potential improvements in formula protein are not unduly restricted.

The Infant Formula Council also endorses the recommended minimum and maximum values for iron at 0.15 and 2.0 mg/100 Kcal and further recommends that formulas should contain at least 1 mg of iron/100 Kcal in order to be labeled "with iron" or "iron fortified." Furthermore, we believe formulas which contain less than 1 mg of iron/100 Kcal should continue to carry a label statement indicating that additional iron should be supplied from other sources.

With respect to inositol, choline and biotin, Dr. Woodruff of the American Academy of Pediatrics noted in his testimony before Congress on March 6 that the levels in the table should not be interpreted as strict minimum values for milk-based formulas since these are the average values usually found in these formulas. Any requirement for the presence of these substances should be limited to milk-substitute formulas.

It is emphasized that the Infant Formula Council currently subscribes to the guidelines of the Committee on Nutrition of the American Academy of Pediatrics (and the Codex Alimentarius Commission). More importantly, we reaffirm the industry's commitment to following these minimum nutrient levels for all formulas for normal, full-term infants whether or not the recommendations are codified into regulatory requirements.

Now, I wish to address a few aspects of the Committee's recommendations that, if directly incorporated into regulatory requirements, will present significant problems. First, with reference to iodine, it is known that current U.S. milk supplies provide iodine at levels significantly higher than dietary requirements. It should be stressed that although infant formulas manufactured from current milk supplies provide iodine at levels above nutrient needs, they pose no health risk. We agree that programs for reducing the iodine levels in the milk supply should be undertaken by responsible agencies and industries, but we must note that conformance with the proposed maximum value of 50 mcg/100 Kcal of formula is not consistently achievable with

current milk supplies. There are no practical means presently available for removing iodine from milk and until effective programs for reducing iodine levels in milk supplies can be implemented, there will be no way to assure that all batches of formula fall below the proposed maximum. Considering the absence of health risk, establishment of a 50 mcg/100 Kcal regulatory limit for iodine is inappropriate, and disruptions of supply will occur if the proposed maximum for iodine is established and enforced as an absolute limit.

Next, regarding fluoride, the Committee's recommended 60 mcg/100 Kcal target maximum is appropriate for the purpose of assuring a consistently low fluoride intake from formula, thereby assisting the physician in determining total fluoride intake and enabling better selection of suitable sources of fluoride for the infant. It should be noted, however, that fluoride intakes nominally higher than 60 mcg/100 Kcal will have no adverse health consequences, and careful consideration should be given to this matter before imposition of an absolute maximum. We believe it would be reasonable to establish a proposed maximum of 80 mcg fluoride/100 Kcal as a guideline and we would recommend that a label claim for fluoride not be required since formula is neither perceived nor intended to be a significant source of dietary fluoride. A label claim would be confusing to the consumer and the label is not an appropriate medium for reaching physicians and dentists. Manufacturers will continue to provide physicians and dentists with product information relevant to decisions about dietary fluoride supplementation.

Infant formulas containing appropriate sources of nutrients within the levels recommended by the Committee on Nutrition have been shown to be adequate for good growth and development when used as substitutes for human milk. However, there are ongoing considerations as to whether addition of any other substances may improve the nutritional value of these formulas. There are some substances and trace minerals in human milk which may be present in infant formulas but at lower levels than in human milk. Some of these substances are found in cow's milk and are therefore present in milk-based formulas, but not present in milk-substitute formulas. Most of these substances, such as cholesterol, taurine, and carnitine are synthesized by the infant but it is not clearly established that any of them should be included in the diet. We concur with recommendations of the FASEB Committee report, there is a need for further clinical study to determine whether addition of these substances to formulas may provide any beneficial effects. Insofar as current regulatory requirements would classify any substance which is not an approved ingredient or nutrient as either a new food additive or a new drug, inclusion of such substances (e.g., taurine) invokes regulatory provisions that makes it very

difficult to conduct such studies. We therefore recommend that specific provisions be made for adding substances known to be present in human milk but whose nutritional or metabolic significance is not established. Similar considerations apply to trace minerals which may be of nutritional significance, e.g., selenium, molybdenum and chromium.

With regard to codifying the presented guidelines into regulatory provisions that would best accommodate regulatory, commercial and, most importantly, public interests, we recommend the following:

1. Updating of Food and Drug Administration's 1971 regulations (i.e., 21 CFR 105.65) for infant foods to embrace the most recent Committee on Nutrition/American Academy of Pediatrics guidelines, with the exceptions noted earlier, as the most efficient and expedient route to regulating the nutrient composition of infant formula.

2. The minimum and maximum nutrient levels established by the recommended regulations should be interpreted and enforced in the context of Good Manufacturing Practice provisions.

3. Manufacturers should, consistent with principles of current Good Manufacturing Practices, continue to develop and maintain appropriate analytical data and test results to document ongoing compliance with applicable nutrient composition regulations and be prepared to review such data in response to appropriate requests from the Food and Drug Administration.

4. Within the context of appropriately revised regulations, provisions should be made for exempting specialty formula products that must, for medical reasons, fall outside some of the prescribed nutrient composition ranges.

Conclusion/Summary

In conclusion, the Infant Formula Council concurs with the American Academy of Pediatrics Committee on Nutrition position on breast-feeding and endorses the Committee's proposed minimum nutrient guidelines for infant formulas. The Infant Formula Council concurs with the recent recommendation of the Committee as reflecting the best nutrient information available and, with the few minor exceptions noted, supports incorporation of the Committee's proposals into an updated version of current regulations on infant formula labeling. (A copy of the Committee on Nutrition of the American Academy of Pediatrics table referred to is attached.)

As regulations are updated for ensuring nutrient composition of current formulas, the Infant Formula Council requests development of regulatory provisions that will encourage research and permit incorporation of newly recognized nutrients to make available improved formulas and new formulas to meet special dietary needs.

We also reemphasize our recommendations that any new nutrient composition regulations be interpreted and enforced in accordance with established principles of Good Manufacturing Practice regulations. Finally, we agree with the recommendation that manufacturers maintain and allow specific records review, as appropriately requested by Food and Drug Administration, to verify compliance within Good Manufacturing Practice principles, established standards, and regulations.

MERICAN ACADEMY PEDIATRICS
Department of Government Liaison
1600 North Kent Street
Arlington, Virginia 22209

APPENDIX

(Revised - February 28, 1980)

RECOMMENDED NUTRIENT LEVELS OF INFANT FORMULAS (per 100 Kcal)

AAP Committee on Nutrition 1980 Recommendations

Nutrient	Minimum	Maximum
Protein (gm)	1.8	4.5
Fat		
(gm)	3.3	6.0
(% cal)	30.0	54.0
Essential fatty acis (linoleate)		
(% cal)	3.0	--
(mg)	300.0	--
Vitamins		
A (IU)	250.0 (75 μg)*	750.0 (225 μg)*
D (IU)	60.0	100.0
K (μg)	4.0	--
E (IU)	0.7 (at least 0.7 IU/gm linoleic acid)	--
C (ascorbic acid)(mg)	8.0	--
B_1(thiamine (μg)	40.0	--
B_2(riboflavin.)(μg)	60.0	--
B_6(pyridoxine)(μg)	35.0 (at least 15 μg/gm of protein in formula)	--
B_{12}(μg)	0.15	--
Niacin (equivalent)(mg)	1.0	--
Folic acid (μg)	4.0	--
Pantothenic acid (μg)	300.0	--
Biotin (μg)	1.5**	--
Choline(mg)	7.0**	--
Inositol (mg)	4.0**	--
Minerals		
Calcium (mg)	50.0†	--
Phosphorus (mg)	25.0†	--
Magnesium (mg)	6.0	--
Iron (mg)	0.15	2.0
Iodine (μg)	5.0	50.0
Zinc (mg)	0.5	
Copper (μg)	60.0	
Manganese (μg)	5.0	
Sodium (mg)	20.0 (6 mEq)‡	60.0 (17 mEq‡
Potassium (mg)	80.0 (14 mEq)‡	150.0 (26 mEq‡
Chloride (mg)	55.0 (11 mEq)‡	115.0 (22 mEq‡

(Formula should be made with water low in fluoride and in any case contain less than 60 micrograms per 100 Kcal.)

*Retinol equivalents
†Calcium to phosphorus ratio should be no less than 1.0 nor more than 2.0
‡Milliequivalent for 670 kcal/liter of formula
**Average present in milk-base formulas; should be included in this amount in other

Mr. GELARDI. Thank you.

As we indicated, Mr. Chairman, in our testimony before your counterpart committee in the House, the council supports any reasonable action, legislative or regulatory, that will effectively help assure the continued availability of sound infant formulas.

However, legislative provisions which might disrupt the supply of infant formula, deter improvements in infant formulas and erect disincentives to the development of formulas for infants having special needs cannot be supported. With those concerns in mind, I will direct my comments to the substantive provisions of Senate bill 2490, since we endorse the House bill and are in general concurrence with its provisions.

The council fully supports the establishment of appropriate nutrient levels for infant formulas. Because of the complicated technical nature of nutrition and biochemistry, we believe that designation of specific levels by statute is less desirable than setting them by the regulatory process.

Additionally, a mandatory directive to the Secretary to establish standards of identity and quality for infant formulas would be far more rigid than mandating that the Secretary establish appropriate nutrient levels.

Senator METZENBAUM. I have a little trouble in comprehending the point you are making, that you believe that designation of specific levels by statute is less desirable. That sentence follows a few seconds earlier your statement that you support the House bill.

Mr. GELARDI. We do endorse the House bill. We are receptive to inclusion of nutrients in the recipe, as provided by the bill. We do not think that it as preferable as requiring the Secretary to establish those levels. You set a precedent by putting into the legislation, in the statutory form, specific ingredients, which subjects are the possibility of future recipe changes, perhaps based more on political motivation than current involvement. It might be not quite in consistent interest of the public as well as in the scientific community to make such a precedence.

We do believe, however, that the House bill does incorporate appropriate nutrients in the table as recommended by the American Academy of Pediatrics.

Senator METZENBAUM. All right.

Mr. GELARDI. The council has a concern with respect to specialty formulas with respect to bill S. 2490, as drafted, since the formulas would be subject to the bill's provisions until specifically exempted. This could wreak havoc on both the specialty formula industry and consumers, because many specialty formulas would technically be adulterated unless timely reaction is taken by the Secretary.

The committee discussed timely action this morning. An approach which would exempt properly labeled specialty formulas from portions of the bill in the first instance would help assure the continued availability of these formulas to infants dependent upon them and would be clearly in the public interest. Unless care is taken, these formulas can be overreglated off the market.

Senator METZENBAUM. Mr. Gelardi, under that approach, would not the soy-based products used for lactose intolerance in infants be characterized as specialty formula?

Mr. GELARDI. If you are speaking about Neo-Mull-Soy, Cho-Free, and other soy-based formulas of manufacturers, we would not consider them to be specialty formulas within the meaning of the act. I do not believe that was what was intended on the House side. That would be considered as a specialty formula. We can talk more about that later, if you like.

Senator METZENBAUM. I think that is the kind of subject that perhaps the staff and your own legal counsel might be able to come to some understanding on.

Mr. GELARDI. That is not considered by us to be a specialty formula, nor as contained in the House bill.

The industry fully supports and is committed to appropriate ingredient testing to assure that manufactured formula contains required nutrients. The materials which we have submitted for the record detail current industry practice in this area.

The language of the proposed bill borders on, if it does not constitute, a preclearance requirement. The language requires a satisfactory showing, but does not specify how such a showing is made.

It might be easily incorrectly assumed that the manufacturer must await word from the Secretary that the submission is satisfactory. Because such a preclearance provision could disrupt the availability of formula. FDA, the council and the House of Representatives are all on record as opposing any preclearance requirement.

Senator METZENBAUM. The intent is not to provide a preclearance requirement, and again this may be a question of sitting down with staff and working out language. I do not think this is a matter particularly at issue.

Mr. GELARDI. Thank you, Senator. We would appreciate the opportunity to do that.

I will skip to the next point, because I think that covers it.

Processors now make and retain detailed records regarding the distribution of their infant formulas. Such records are required under FDA's low-acid canned food regulations for liquid infant formulas and the same detailed records are kept voluntarily for powdered formulas.

The council is unaware of any instance where a processor's distribution records have been inadequate and, therefore, questions the need for a statutory distribution record requirement.

The council is greatly concerned about granting FDA the expanded power to remove records from the processing facility. First, and of utmost importance to the public health, are the consequences if FDA removed distribution records and misplaced them. If a recall of product was subsequently necessary, both the company and the consumer could suffer needlessly because of FDA's mistake.

Senator METZENBAUM. Would you have any difficulty if removal of the records was prohibited, but authority to copy those records was given to the FDA?

Mr. GELARDI. We would have no problem with that whatsoever. We would like to be sure that records are specified, however, such that records that are available to nutrient-level requirements and other aspects of distribution that would help to monitor the recall, if necessary, was what was looked at, and not, obviously, financial records, and things of that nature.

Senator METZENBAUM. It probably also is an area in which some language, clarification, could be worked out.

Mr. GELARDI. Fine. Glad to hear that.

The Food and Drug Administration currently has authority to obtain seizures, authority to seek injunctions, and the availability of criminal prosecution.

Since the public health is already adequately served by existing extensive FDA authority and since distribution of formula to consumers might be arbitrarily disrupted by the improper exercise of administrative detention authority, the council opposes granting the FDA authority to order administrative detention.

In our opinion, administrative detention authority might be misused or used in a manner that could seriously and unnecessarily disrupt the availability of infant formula in this country.

For example, whether or not it related to the safety of the finished product, an inspector's impression of manufacturing procedures could lead him erroneously to conclude that the finished product should be subject to administrative detention.

Therefore, we oppose granting unbridled authority that could halt the flow of formula products based solely on the conclusion of an inspector in the field that a formula product may be adulterated or misbranded, without regard to the significance of the alleged adulteration or misbranding. The proposed provision is especially onerous since all of this would occur before the manufacturer is entitled to any review, even if the inspector was absolutely in error.

Senator METZENBAUM. I wonder if you would not accept the concept that when, an inspector is very strongly convinced that a formula product ought to be detained, some method of prompt review be established?

Mr. GELARDI. Well, one of the provisions of the bill that we strongly support—and that is true of the House bill as well—is that the manufacturer must assure and must certify, notify FDA that proper nutrients are in the formula. I think it is quite clear that with that kind of requirement that the manufacturer could not certify that they were shipping illegal products. In other words, the real problem that developed, the incident that caused this, was due to the fact that the manufacturer was not aware of the fact that a test had not been made. They had to certify to the fact that nutrients had been tested for and were present under both laws that are proposed. We fail to see what granting FDA this additional detention authority would really accomplish from a public health purpose. It could be very serious, a very serious disruption.

Let me give you an example.

In some of the products available, they may have a turnover, or shelf life, in terms of amount of time it is on the shelf in the supermarket, a turnover time of maybe 2 weeks. If FDA has authority to detain for 30 days, especially for some of the different formulas, children and parents would be without formula. We do not see that it serves a really useful health purpose. That is why I raise it in that context.

Senator METZENBAUM. We are inquiring into your position and I am not sure we are in agreement with it, but there may be some

way we can find some livable, acceptable compromise on it. We would have to discuss it with you.

Mr. GELARDI. Fine. We appreciate that.

The council believes that labeling is best left to administrative discretion rather than statutory direction. Such discretion on the part of FDA can deal with the many special factors which simply are impossible to consider in a statutory context.

The council also points out that industry has been uniquely responsive to consumer desires in the area of labeling of infant formulas.

Recently, as an example, concern was expressed to the council that illiterate mothers might misuse concentrated formula by failing to add water. Attention was thereupon devoted to determining how best to convey dilution requirements to illiterates.

Colored can coding, as currently in bill S. 2490, was explored as one such method, but it was determined such an approach would be considerably less effective than "add-water" symbols.

Color coding requires a considerable degree of user education, could pose problems for those who are colorblind, might cause confusion with related products, and does not recognize particular ethnic and other perceptions. On the other hand, an appropriate symbol is self-explanatory. Thus, consumer tested add-water symbols are now on the labels of concentrated infant formula.

Other provisions in bill S. 2490 would require labeling in the nature of patient package inserts, which are currently being cautiously tested by FDA with respect to certain drugs.

There is today considerable controversy whether such inserts are the best means of communicating information to consumers, whether the added cost to the consumer is commensurate with the anticipated benefit, or, indeed, whether such inserts would have a beneficial rather than a deleterious effect.

The council also wishes to point out the unique relationship which exists between the mother and the child, and the health professional. Any statutorily mandated labeling which might differ from the personalized advice of the health professional could cause needless questioning and anxiety on the part of parents and detract from the professional/patient relationship to the detriment of the infant.

With respect to label information for the practitioner, infant formula companies already do a great deal in this area. The council submits, therefore, that statutory directives are unnecessary and would be detrimental and confusing.

Senator METZENBAUM. Would you, Mr. Gelardi, be supportive of statutory language requiring FDA to come up with labeling requirements within a period of X number of days?

My point is—and Senator Schweiker has stated it as well—that the bureaucratic delays that occur in so many of these areas become very frustrating to those of us who think some action is needed. I would urge upon you that you give some thought to that approach. Some of us feel labeling is important. You may have a point and question whether or not it ought to be a statutory requirement, or by statute we ought to require FDA to act.

Frankly, we would like to eliminate the intolerable delays that governmental agencies take in finally arriving at a conclusion. I

urge upon you that you give some thought to some approach such as that.

Mr. GELARDI. We certainly would give consideration to it. FDA does have labeling authority, as you point out. The agency has also undertaken, as I indicated, with the dilution symbol, a voluntary program, to assure appropriate communication. I think it is important to stress that we need to be sure of what we are trying to accomplish with changes in labeling. That is an area where there has not been and is not now a major problem as far as consumers and parents are concerned.

I would like to point out again that infant formulas are not new. There are millions and millions of youngsters and parents who for over 60 years have had infant formula, which is a vast improvement on the very unhealthy products that used to exist prior to that. There were unhealthy products that existed prior to that that caused rickets, scurvy, all kinds of problems. We have for over 60 years now had these products on the shelf for generations of Americans. I find it difficult to believe that we have a tremendously urgent problem with respect to particularly the use of the kinds of things that are contemplated by the legislation. We will give it consideration, Senator.

Senator METZENBAUM. I am not sure I would agree with you that the record has been that great, and certainly the witnesses this morning would very definitely not agree.

Mr. GELARDI. We do not minimize in any way the particular incident that took place.

Under current laws, products can be exported if they conform to specifications of foreign purchasers and are not in conflict with the laws of the country to which they are exported.

Bill S. 2490 would restrict the above by adding the condition that the formula conforms to our law, even though it would never be consumed in this country. This would be the case under this provision even if a medically valid need existed in that foreign country for a formula containing such a recipe, and even if the formula conformed to all the country's applicable rules and the vitamin or mineral content was clearly labeled.

Many countries follow the guidelines of the Codex Alimentarius Commission which may differ slightly from U.S. regulations. Additionally, they may adopt their own standards which differ from both Codex and U.S. standards.

Problems have not been experienced with respect to the export provisions of current section 801(d), but frustrating and senseless results can occur unless the export provisions of bill S. 2490 are dropped or modified.

Senator METZENBAUM. You have heard my question to Dr. Goyan before. Syntex could have exported, except for the fact that it was manufactured for interstate commerce.

Do you think it would have been right for them to export under those circumstances?

Mr. GELARDI. Mr. Chairman, I would like to submit for the record a letter from the Syntex Corp. which they provided me at my request, at the council's request, concerning just what did happen with respect to their low chloride formula in terms of overseas shipment. I think it clearly points out that the problem, if

anything, might have been in the direction of the fact that all of this food was destroyed. But they clearly did not ship any chloride product overseas once they knew the deficiency. They did not ship any of those products in the United States after that discovery, with the exception of the fact that there were certain doctors who felt that certain formula, the only one available, had to be used by those children, and they did that only specifically after getting the approval of the Food and Drug Administration. Perhaps we can submit that for the record.

Senator METZENBAUM. We will be happy to have that. I hope it will answer the question of what they considered doing with the product when they indicated they were considering sending it overseas.

Mr. GELARDI. If I might clarify that, what happened was, a charitable group asked them whether they could have the formula for use overseas, and they could have it to be used in conjuction with specific programs for people who had no nutrition. I will read the letter in that part:

> The charitable organizations gave assurances they would be given as dietary supplements for starving people and would also be accompanied by other feeds which, would supply adequate chloride. Such a donation, as you know, receives the same tax treatment as if a product were destroyed. Syntex was not trying to sell product and would in no way profit from this donation.

[The letter referred to follows:]

SYNTEX CORPORATION
3401 HILLVIEW AVENUE
PALO ALTO, CALIF. 94304

REGULATORY AFFAIRS

June 10, 1980

Mr. Robert Gelardi
Infant Formula Council
5775 Peachtree-Dunwoody Road
Suite 500-F
Atlanta, Georgia 30342

Dear Mr. Gelardi:

You asked that Syntex clarify the record concerning allegations made that the company shipped infant formula products either abroad or in the United States after it was discovered that they were manufactured with low levels of chloride.

No low chloride products were shipped abroad after discovery of this deficiency.

No low chloride products were shipped in the United States after discovery of this deficiency, unless specifically requested by physicians and specifically approved by the United States Food and Drug Administration.

The allegations concerning the export of product we believe stem from the following events. After hearing of the recall of the infant formulas, a non-profit relief organization asked Syntex whether it could donate those protein-rich products. The charitable organization gave assurances that they would be given as a dietary supplement for starving people and would always be accompanied by other foods which would supply adequate chloride. Such a donation, as you know, receives the same tax treatment as if the product were destroyed; Syntex was not trying to sell the product and would in no way profit from this donation. Syntex sought FDA's permission to make the donation and it was denied. Hence no chloride deficient product was sent abroad.

Concerning domestic shipments, as soon as the recall was initiated in August, 1979, all shipments of the products ceased. Shortly thereafter, Syntex began to receive telephone calls from physicians whose patients could not use other infant formulas. They requested from Syntex special supplies of the low chloride product until Syntex could provide newly manufactured, nutritionally complete formulas. As you know, Neo-Mull-Soy is both corn-free and lactose-free and Cho-Free is the only infant formula available in the United States that is carbohydrate-free and corn-free. Both formulas are consumed by infants who cannot tolerate normal milk products.

After receiving these requests, Syntex contacted the FDA to determine if it would approve shipments of the recalled formulas for use by children who could not use other products. FDA granted permission and requested that it be kept fully informed of the specifics of each of these shipments. Syntex supplied to FDA a record of each shipment made including such background information as the patient's condition, age and reason for needing the formula.

When the shipments were made, the physicians who received the products were reminded by Syntex that the formula was low in chloride and that they needed to insure that the patient's electrolyte balance was maintained. All these shipments were made free of charge by Syntex.

Syntex did not make any other shipments of the recalled formula. After the products were reformulated with sufficient chloride and their relaunch was approved by the FDA, these special shipments ceased.

If I can be of further help to you, please let me know.

Sincerely,

Virgil Thompson

67-931 O - 80 - 9

Senator METZENBAUM. I am not sure it really answers the question. Be that as it may, reading your testimony in connection with the export provisions, I gather that all you are saying is that some other foreign laws require formulas to contain a vitamin or mineral in excess of maximum established U.S. regulation, and that that concerns you. You may not be able to comply with other foreign laws. Therefore would it be acceptable to you that we have the export provisions in the language with a proviso that if a foreign country actually requires some variation, then formula manufacturers in complying with that variation would not be violating U.S. laws?

Mr. GELARDI. That seems a reasonable compromise initially. I would like to really think about that, Senator, and confer with various members of the council to see how that might be worked out. We should recognize that the United States and infant formula manufacturers in the United States supply a very, very small proportion of the formulas overseas.

Senator METZENBAUM. We will be happy to see if we can work out something with you on that provision as well.

Mr. GELARDI. In conclusion, Mr. Chairman, the Infant Formula Council looks forward to working with the Senate, FDA and other interested parties so that a bill can be enacted which benefits and enlarges even more the protection afforded to consumers of infant formulas and their parents. The council shares a common desire with the committee to see that a bill wholly responsive to and in the best interests of infant health and nutrition is enacted.

Senator METZENBAUM. Your testimony is helpful. Our staff stands prepared to meet with you to try to work out some of these areas. We do have intentions of moving this legislation very rapidly. I would urge you to contact the staff very rapidly.

Senator Schweiker.

Senator SCHWEIKER. I have no questions. I do want to say that obviously we are dealing with a serious problem. I am impressed to see the industry come forward and endorse a regulatory bill. Not many industries have done that around here, even when there have been some serious problems. I commend you for that position.

Mr. GELARDI. Thank you

[The prepared statements of Mr. Gelardi, and Dr. Sauls, Jr., follow:]

STATEMENT OF ROBERT C. GELARDI, EXECUTIVE DIRECTOR
THE INFANT FORMULA COUNCIL, BEFORE THE
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES

June 12, 1980

Thank you for the opportunity to appear today on behalf of the Infant Formula Council. The infant formula industry is acutely aware of its responsibility with respect to infant nutrition and health. We, thus, concur with the intent of legislation to foster infant health by assuring the appropriate nutritional content of infant formulas.

The members of the Infant Formula Council recognize that infant formulas are often the sole source of nutrition for infants, and that design, manufacture, and control of infant formulas, therefore, require special care. This special care has been exercised for a long period of time and has resulted in a remarkable record of consistent high quality products over the years. Further recognizing the importance of human milk and breastfeeding, the industry fully acknowledges breastfeeding as the preferred mode of feeding and constantly works to improve its formulas to incorporate as much as possible the nutritional benefits provided by human milk.

We also recognize that following a major recall last year of one manufacturer's infant formula, questions were raised concerning how best to assure that those who rely on infant formula can remain confident that formula meets the nutritional needs of infants. The industry supports the efforts of the Food and Drug Administration, through its public hearing process, to thoroughly examine this question, and recognizes the need for appropriate

regulatory policy with respect to infant formula. The Infant Formula Council participated in both a Public Meeting on Quality Assurance and Quality Control Procedures, and a Public Hearing on Nutrient Content of Infant Formulas, held earlier this year by the Food and Drug Administration. With the Chairman's permission we would like to submit the text of our presentations for inclusion in the record of these proceedings.

In addition, the industry is committed to following FDA's January 4, 1980 revised recall procedures if a recall of a distributed infant formula becomes necessary. Also, Council members adhere to the interim guidelines for nutrient composition of infant formulas published by FDA on March 18, 1980 (45 Fed. Reg. 17206). These guidelines are based on recommendations made by the Committee on Nutrition of the American Academy of Pediatrics.

In addition to recent FDA initiated efforts to assure the compositional quality of infant formulas, the industry has undertaken independent and voluntary measures to the same end. Members of the Infant Formula Council have conducted an extensive review of industry procedures, practices and policies to assure that the highest quality infant formulas possible are being provided. As part of this review, the industry submitted a detailed description of its quality control and clinical testing procedures to the Food and Drug Administration. Additionally, an industry commitment has been affirmed not only with respect to current and proposed FDA Good Manufacturing Practices and Low-Acid Canned Food Regulations, but also with respect to practices beyond those proposed, including raw material control, checking of product

composition, plant cleanliness, and preparation and maintenance of detailed records.

We believe that these industry practices are largely responsible for the industry's excellent decades-long record of high quality products. We are confident that strict adherence to them will result in further progress towards even higher quality products in future years.

Mr. Chairman, the Council supports appropriate action that will assure the public of the continued availability of nutritionally sound infant formulas. As we indicated in our testimony before your counterpart Committee in the House, the Council supports any reasonable action, legislative or regulatory, that will effectively achieve this purpose.

However, legislative provisions which might disrupt the supply of infant formula, deter improvements in infant formulas or erect disincentives to the development of formulas for infants having special needs cannot be supported. With those concerns in mind, I will direct my comments to the substantive provisions of Senate Bill 2490, since we endorse the House Bill and are in general concurrence with its provisions. We believe this approach will be most useful as our specific comments on Bill 2490 also will provide insight into industry's position on the House Bill.

STANDARDS OF IDENTITY AND QUALITY AND REQUIRED NUTRIENT LEVELS

The Council fully supports the establishment of appropriate nutrient levels for infant formulas. Such levels can be established either by requiring

FDA to set appropriate nutrient levels or, less preferably, by adopting appropriate levels by statute and delegating to the Secretary the power to adjust those levels based on advances in our understanding of infant nutrition. Because of the complicated technical nature of nutrition and biochemistry, we believe that designation of specific levels by statute is less desirable, when this can be accomplished more effectively by the regulatory process.

A mandatory directive to the Secretary to establish standards of identity and quality for infant formulas, would be far more rigid than mandating that the Secretary establish appropriate nutrient levels. Such rigidity would not be in the best interests of public health.

The standards of identity regulations have been designed to prevent economic fraud against American consumers. For example, before a particular product which has a standard of identity can be designated by name, it first must meet compositional requirements with respect to levels of ingredients, the primary importance of which are economic. Thus, consumers know that the product contains all of the valuable constituents which, through purchasing and consuming, they have come to expect from that product.

The FDA procedural framework for the establishment of "standards of identity" regulations involves the holding of evidentiary type legal hearings which are cumbersome and enormously time consuming. They also have the practical effect of holding the regulations fixed once established.

"Standards of identity" regulations would not allow the composition of infant formulas to easily and quickly change in response to advances in knowledge of infant nutrition. Historically, some of FDA's greatest delays involve attempts to change food standards of identity, such as the peanut butter hearings in the early 1960's which dragged on for over 10 years.

If the legislative intent in requiring "standards of identity" is to assure that infant formula contains appropriate nutrient levels, this could more readily be done through requiring the Secretary to establish appropriate nutrient levels and to amend labeling regulations to require that products contain what is prescribed.

Such regulations enacted under the general provisions of the Food, Drug and Cosmetic Act can be constantly updated by the notice and rulemaking procedure. Thus all interested parties have the opportunity to comment on any portion of a proposal and the FDA must consider these comments prior to establishment of the regulation. This, most importantly, would permit advancements in nutritional knowledge to be timely incorporated into infant formulas.

EXEMPTION FOR SPECIALTY FORMULAS

Certain specialty formulas are manufactured and labeled for use by infants who have inborn errors of metabolism, low birth weight or other unusual medical or dietary problems.

As Bill 2490 is drafted, such specialty formulas would be subject to the Bill's provisions until specifically exempted. This could wreak havoc on

both the specialty formula industry and consumers, because many specialty formulas would technically be "adulterated" unless timely action is taken by the Secretary. An approach which would exempt properly labeled specialty formulas from portions of the Bill in the first instance would help assure the continued availability of these formula to infants dependent upon them and would be clearly in the public interest. Unless care is taken, these formulas can be over-regulated off the market.

The Council submits that discretionary power vested in the Secretary to exempt speciality formulas is insufficient to assure the users of specialty formula in this country that the supply of such formulas will not be disrupted. Appropriate assurances that specialty formulas will be exempted from arbitrary nutritional levels can be made only if the Secretary is mandated to exempt such formulas or if such formulas are exempted by statute in the first instance.

PERIODIC AND PREMARKET SUBMISSION OF TEST RESULTS

The industry fully supports and is committed to appropriate ingredient testing to assure that manufactured formula contains required nutrients. The materials which we have submitted for the record detail current industry practice in this area.

In the manufacture of complex products such as infant formulas, consistent success can only be achieved by constant diligence and attention to essential detail. These practices are generally grouped under the term

good manufacturing practices. As I have mentioned, the industry has committed itself not only to those good manufacturing practices currently required or proposed by FDA, but also to additional, even more stringent, practices. These additional practices help guarantee the quality of infant formulas and serve to provide infants an extra measure of protection in the formulas they rely upon. The Council, while adhering voluntarily to these practices, would support appropriate FDA incorporation of these practices into regulations.

The Council does not believe, however, that the periodic and premarket submission of test results to FDA will provide the public with any greater protection than it currently enjoys. FDA receives thousands of submissions of the type contemplated for other products it regulates, and it is not uncommon that such submissions are not reviewed in either a timely or comprehensive manner. A statutory submission requirement, therefore, would impose additional burdens without providing any real benefits.

The language of the proposed Bill also borders on, if it does not constitute, a preclearance requirement. The language requires a "satisfactory" showing, but does not specify how such a showing is made. It might be easily incorrectly assumed that the manufacturer must await word from the Secretary that the submission is satisfactory. Because such a preclearance provision could disrupt the availability of formula, FDA, the Council and the House of Representatives are all on record as opposing any preclearance requirement.

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Adequate assurances of safety, on the other hand, can be made available in the form of increased FDA inspectional authority, authority which Bill 2490 gives to FDA. The Council supports FDA's increased authority to view processor records dealing with nutritional content. Further the Council believes that an FDA investigator's first hand review of such records during factory inspections affords more protection to the public health than a protracted document submission procedure. For these reasons, the Council believes that notice to the Secretary upon reformulation and before new product marketing will best serve the public.

NOTIFICATION PROVISIONS

According to proposed Bill 2490, when a processor discovers that one of his distributed formulas is adulterated pursuant to new section 402(f), or misbranded pursuant to new section 403(q), he must notify the Secretary on two occasions: first, after acquiring and verifying the information and second, upon instituting a recall. The Council supports FDA knowledge of and advice on situations of the type described in these provisions. As a practical matter, however, after the initial notification, there is an interface between the processor and FDA which will continue until the matter is corrected. Therefore, the Council believes that the second notification, that is upon instituting a recall, is duplicative and unnecessary.

RECORDKEEPING REQUIREMENTS

Processors now make and retain detailed records regarding the distribution of their infant formulas. Such records are required under FDA's

Low-Acid Canned Food Regulations for liquid infant formulas and the same detailed records are kept voluntarily for powdered formulas. The Council is unaware of any instance where a processor's distribution records have been inadequate and, therefore, questions the need for a statutory distribution record requirement.

The Council is greatly concerned about granting FDA the expanded power to remove records from the processing facility. Two reasons underlie this concern. First, and of utmost importance to the public health, are the consequences if FDA removed distribution records and misplaced them. If a recall of product was subsequently necessary, both the company and consumer could suffer needlessly because of FDA's mistake. Second, a company's distribution records would be of great benefit to a competitor, so there is a justifiable need to restrict the availability of those documents. There simply are insufficient safeguards under the Freedom of Information Act. Companies, therefore, have a right to protect their records and keep them under their exclusive control. Duplicating machines are available in processors' plants and FDA should utilize duplicates, with the further assurance that all copies made are confidential.

With respect to the records assuring compliance with the nutritional levels, the Council supports such reasonable recordkeeping requirements. For reasons stated earlier, however, the Council does not believe that the submission of reports best protects the public health. A provision requiring the making and retention of records, coupled with notification to FDA and FDA inspectional access of records, is the preferable method to verify the quality of infant formula.

ADMINISTRATIVE DETENTION

The FDA currently has authority to obtain seizures (which can "freeze" a product while the question of its compliance is determined by the courts), authority to seek injunctions (which can enjoin the shipment of a violative product) and the availability of criminal prosecution (which can be used to invoke fines and jail sentences for violations). Since the public health purpose is already adequately served by the extensive FDA authority outlined above and since distribution of formula to consumers might be arbitrarily disrupted by the improper exercise of administrative detention authority, the Council opposes granting the FDA authority to order administrative detention.

As drafted, Bill 2490 has delegated far too much discretion to FDA inspectors. Those individuals would be entitled to stop the movement of any formula product believed to be adulterated or misbranded for at least 20 days, a period which can be extended to 30 days if agreed to by the Secretary.

In our opinion, administrative detention authority might be misused or used in a manner that could seriously and unnecessarily disrupt the availability of infant formula in this country. For example, whether or not it related to the safety of the finished product, an inspector's impression of manufacturing procedures could lead him erroneously to conclude that the finished product should be subject to administrative detention. Therefore,

we oppose granting unbridled authority that could halt the flow of formula products based solely on the conclusion of an inspector in the field that a formula product may be adulterated or misbranded without regard to the significance of the alleged adulteration or misbranding. The proposed provision is especially onerous since all of this would occur before the manufacturer is entitled to any review, even if the inspector was absolutely in error. Thus, it could work a serious disservice on both the manufacturer and the public.

RECORD INSPECTION AUTHORITY

The Council, as noted in earlier comments, feels that nutrient composition record inspection authority is preferable to submissions of reports to assure that infant formulas are safe and nutritious.

LABELING REQUIREMENTS

Labeling of infant formulas, whether that labeling is required on the container or on a leaflet, is a subject involving complex issues. The Council believes that such labeling is best left to administrative discretion rather than statutory direction. Such discretion on the part of FDA can deal with the many special factors which simply are impossible to consider in a statutory context.

The Council also points out that industry has been uniquely responsive to consumer desires in the area of labeling of infant formulas. Recently, as an example, concern was expressed to the Council that illiterate mothers might misuse concentrated formula by failing to add water. Attention was

thereupon devoted to determining how best to convey dilution requirements to illiterates. Colored can coding, as currently in Bill 2490, was explored as one such method, but it was determined such an approach would be considerably less effective than "add-water" symbols. Color coding requires a considerable degree of user education, could pose problems for those who are color-blind, might cause confusion with related products and does not recognize particular ethnic and other perceptions. On the other hand, an appropriate symbol is self-explanatory. Thus, consumer tested "add-water" symbols are now on, or in the process of being added to, the labels of concentrated infant formula.

Other provisions in Bill 2490 would require labeling in the nature of patient package inserts, which are currently being cautiously tested by FDA with respect to certain drugs. There is today considerable controversy whether such inserts are the best means of communicating information to consumers, whether the added cost to the consumer is commensurate with the anticipated benefit, or, indeed, whether such inserts would have a beneficial rather than a deleterious effect.

The Council also wishes to point out the unique relationship which exists between the mother and child, and the health professional. The health professional customarily consults with the expectant mother and tells her, when appropriate, how to feed formula, what signs to look for in the child, when to seek help, etc. Such advice must necessarily be tailored to the individual mother and child. Any statutorily mandated labeling which might differ from

the personalized advice of the health professional could cause needless questioning and anxiety on the part of parents and detract from the professional/patient relationship to the detriment of the infant.

With respect to label information for the practitioner, infant formula companies already do a great deal in this area. The Council submits, therefore, that statutory directives are unnecessary and would be detrimental and confusing.

EXPORT RESTRICTIONS

Under current laws, products can be exported if they conform to specifications of foreign purchasers and are not in conflict with the laws of the country to which they are exported.

Bill 2490 would restrict the above by adding the condition that the formula conforms to our law, even though it would never be consumed in this country. Thus, if a foreign purchaser desired to buy formula containing, for instance, a vitamin or mineral in excess of a maximum established in the U.S. regulations, a U.S. manufacturer could not manufacture and export such a product. This would be the case under this provision even if a medically valid need existed in that foreign country for a formula containing such a "recipe," and even if the formula conformed to all that country's applicable rules and the vitamin or mineral content was clearly labeled.

Many countries follow the guidelines of the Codex Alimentarius Commission which may differ slightly from United States regulations. Further, countries

may adopt the Codex standard with some modifications which would thus make it different from the U.S. regulations. Additionally, they may adopt their own standards which differ from both Codex and U.S. standards.

Concerning labeling for export, our views on domestic patient package inserts have already been expressed. We likewise do not see the need for such labeling to accompany exported infant formula products as required by Bill 2490. Indeed, the need for user information and its style, content and format are clearly subjects best addressed by the regulatory authorities and health professionals of the countries where the products are to be used.

Problems have not been experienced with respect to the export provisions of current Section 801(d), but frustrating and senseless results can occur under the export provisions of Bill 2490. Therefore, the Council believes the export provisions in Bill 2490 should be deleted.

VIOLATIONS

Bill 2490 imposes a number of new requirements on infant formula processors. A violation of any such provision exposes the violator to a product seizure, to an injunction restraining him from continued production, or to criminal penalties (including fines and prison terms for individuals). In the context of a statute which contains such harsh and potentially disastrous penalties, the specific delineation of precisely which acts or failures to act expose an individual to FDA enforcement action is appropriate and should be incorporated into Bill 2490.

CONCLUSION

Mr. Chairman, on behalf of the Infant Formula Council, I thank you and other members of the Committee for the opportunity to appear before you today to present our views on proposed infant formula legislation. The Council commends the members and their staff for their interest and attention to this important issue. The Council looks forward to working with the Senate, FDA and other interested parties so that a bill can be enacted which benefits and enlarges even more the protection afforded to consumers of infant formulas and their parents. The Council shares a common desire with the Committee to see that a bill wholly responsive to and in the best interests of infant health and nutrition is enacted.

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CLINICAL TESTING OF INFANT FORMULAS

A statement submitted to the
Food and Drug Administration
by the
Infant Formula Council

February 19, 1980

Speaker

Henry S. Sauls, Jr., M.D. FAAP
Vice President Medical Affairs
Ross Laboratories

INTRODUCTION

I appreciate the opportunity to provide information concerning clinical testing on behalf of the Infant Formula Council and the infant formula industry. In order to provide an appropriate perspective on the current industry, it is useful to review briefly the history and basis of infant formula.

HISTORY

Substitutes for breast milk, such as cows' milk and other animal milks, have been used to feed infants from earliest recorded history. Infant feeding utensils dating from 1500 BC have been found, as have first century Roman nursing bottles containing dried remains of milk.

Scientific investigations of breast milk substitutes began in the 19th century and continue today. Through clinical testing, researchers developed modified milk products which were later marketed as infant formulas. Testing and retesting of potential formulas is an integral part of the history of the infant formula industry.

We in the industry are acutely aware of our responsibility for infant health, and we believe our stewardship in clinical research has been excellent. We conduct clinical tests to assure that our ever-evolving

formulas meet the highest nutritional standards. In the next few minutes, I will make some general comments on how formulas are formulated and reformulated, and the judgments necessary to carry out clinical testing in infants.

GENERAL COMMENTS ON EVALUATION OF INFANT FORMULAS

Human milk is the model on which all formulas for normal term infants are based. Therefore, the purpose of the modifications which make formula more appropriate for infants is generally to change the proportion of nutrients of cows' milk to resemble the composition of human milk. Additional goals are to assure that the nutrients are well absorbed and completely meet the nutritional requirements of infants under one year of age. Further recognizing and acknowledging the importance of human milk and breast feeding, the industry fully supports breast feeding as the preferred feeding practice for babies and constantly works to improve its formulas to incorporate as much as possible the nutritional benefits provided by human milk.

As experience with human milk composition has accumulated, wide compositional variations have been measured. For example, protein content may vary from 0.7 to 1.4 g/liter; sodium may vary from 5mEq/liter to 20 mEq/liter; and unsaturated fatty acids may vary from 5 to 45 percent of the total fat depending on the type of fat in the mother's diet. From the

earliest days of infant nutritional research, academic pediatricians and food scientists collaborated to make and test formulas that duplicated these variations. Clinical tests were carried out which showed that normal infants tolerate these wide variations with ease.

With this historical background, nutritionists, physicians, food chemists and others can draw upon a wealth of experience with animal and human nutrition and with knowledge of human milk composition to guide them in formulating and reformulating infant formulas. With literally thousands of facts available, one really never has to "start from scratch" to make an infant formula, as would be the case with a completely new chemical entity.

An illustration of this point is the modern development of soy isolate formulas about twenty years ago. Before soy protein was used in infant formulas, scientists had thoroughly tested soy protein adequacy in animals and man. To make an infant food using soy protein was first a major food technology assignment. Subsequent to this achievement, it was tested in animals and finally in human infants. But the basic formulation of the soy isolate-based infant formula was derived from forty years of experience with milk-based infant formulas.

DEVELOPMENT AND TESTING OF INFANT FORMULAS

Now, I would like to talk about how infant formulas are reformulated, when it is necessary to clinically test new or reformulated products, and how they are clinically evaluated.

Formulation changes are rarely major but generally represent incremental changes in response to new scientific knowledge or internal product research. A formulation change or a new formulation may be first proposed by the product development scientists, a nutritionist/physician team in consultation with academicians, or the change may originate as the result of a new recommendation by an official body such as the Academy of Pediatrics Committee on Nutrition (AAP-CON).

The first step in reformulation is to search the scientific literature and all pertinent available information. Often the contemplated change has been studied, and questions about its effects are already answered by past experience.

Establishment of nutrient specifications

The proposed formulation is then carefully worked out by a team of nutritionists and food scientists who make sure that the formulation is in compliance with the AAP-CON Standards for Infant Formulas, and guidelines of the WHO/FAO Codex Committee on Foods for Special Dietary Uses.

Product formulation

As explained in Dr. Tennyson's presentation, the reformulated product is developed through laboratory and pilot plant experimentation. To assure that specified nutrient levels are being achieved, formulations are subjected to nutrient assays throughout the development phase. The product also must show satisfactory analytical test results and possess acceptable physical stability before it is cleared for administration to humans in clinical trials.

I will now discuss how a reformulation is tested and give examples of what changes prompt which types of studies.

PRECLINICAL TESTING

All nutrients used in an infant formula have had extensive human use before being used in the infant formula. The considerations in animal

testing then become:

- Biological value of the ingredient as a nutrient source in the formulation.
- Biological availability (i.e., absorption and utilization) of the ingredient.

Frequently, animal studies are then appropriate to establish the nutritional quality of individual ingredients, nutrient availability, protein or fat quality and certain other specific characteristics of foods. However, animal studies cannot completely answer all questions of the nutritional adequacy of formulas in human infants because experimental animals have very different nutritional and metabolic needs from humans. Poor response of an animal to an experimental formula could be interpreted as nutritional inadequacy when it was the animal that was inappropriate.

CLINICAL TESTING

When the formula shows satisfactory test results and acceptable stability, and when indicated animal testing is complete, it is ready for evaluation in clinical trials. The decision to evaluate a product clinically and the extent to which it is studied is made by a staff of research physicians and nutritionists and, as appropriate, independent consultants. It is appropriate to conduct clinical trials when there is a scientific question to be asked that can not be answered by other means.

CLINICAL TESTING PROCEDURES

All clinical tests of infant formulas are conducted by academic pediatricians or private pediatric practitioners. Infant formula manufacturers do not have access to large numbers of infants for testing. They do employ or consult with physicians and nutritionists who are knowledgeable and experienced in clinical testing of formulas. They devise research plans in consultation with the physicians who conduct the clinical tests.

The complexity of the studies differs according to the significance of the changes in the formula. Complex studies designed to measure nutrient requirements or nutrient absorption and utilization are performed by researchers who are scientifically qualified, and have access to properly equipped hospital and laboratory facilities. The research protocols are subjected to peer review procedures conducted in accordance with the review procedures of each institution. Less complicated studies may be performed in hospitals or physicians' offices.

Clinical testing procedures fall into three main categories (named here in decreasing order of complexity):

1. Metabolic balance studies in a limited number of infants (five or more) including tests of nitrogen balance, fat absorption and utilization of energy and key minerals depending on the changes made. Metabolic balance studies can be applied to new or reformulated products that are substantially different in composition

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from infant formulas for which there is satisfactory experiences with prior use.

Examples:

a change in all or a significant portion of the fats used in the formula

or

a change in protein type

or

a clinically significant increase or decrease in a mineral level

2. Growth and development studies conducted in infants of appropriate age and size observed for three to four months (90-120 days). Detailed growth indicators (length, weight gain and head circumference), records of formula intake and parameters of development are closely monitored by the pediatric researchers on groups of normal newborn infants (15 or more). Standard laboratory tests may also be performed.

3. Acceptance, tolerance and growth studies of 3 or more months duration in groups of no less than 25-30 newborn babies who are under the care of practicing pediatricians are performed. These tests measure the infants' observed acceptance of the formula, gastrointestinal tolerance (e.g. spitting up and stool characteristics) and growth (length, weight gain and head circumference measurements).

Growth in length and weight gain are sensitive measures of the energy and nutrient availability of the formula. Numerous studies have provided standards against which formula performance can be compared. Although relatively simple to perform, these studies provide valuable information.

If a formulation is substantially different from current or previous products, metabolic, growth, and acceptance and tolerance studies are generally conducted sequentially. If there is substantial experience with the product's composition, but the formulation still requires testing, either or both types 2 or 3 may be conducted. In reformulations which involve only a minor adjustment in an ingredient level, clinical studies may be omitted. All changes require review and formal approval. This includes even very minor changes, processing changes, changes in levels of ingredients and, of course, addition of new ingredients to the formula.

The decision to perform clinical investigation of a reformulation is a judgment reached through consultation with nutritionists and physicians and by utilizing all information derived by the product development staff (re: ingredients, processing techniques and product stability), the historical experience with the formulation, and the clinical experience of both industry pediatricians and academic research pediatricians.

When it is necessary to institute formulation changes based on new information in the literature or to respond to new standards set by the

American Academy of Pediatrics Committee on Nutrition, very careful consideration of all factors is made before the change is proposed. The disciplines of food science, nutrition and clinical medicine are involved to assure consideration is given to all possible effects of the reformulation. I want to emphasize that these changes are usually incremental changes to a formula that has a long history of use. Its safety and efficacy have already been proven and the change is to foster good infant nutrition and health.

An example of such a change is the addition of more iron to infant formula. This change was studied in the 1950's. After numerous clinical studies of iron nutrition in infants, hematologists recommended iron supplementation of infant formula. After numerous studies, the industry increased iron in its formulas in the early 1960's. The incidence of iron deficiency anemia has declined progressively in infants since that time.

Let me discuss for a moment some types of ingredient changes which can be made by relying on analytical data alone. Food commodities generally have standards of identity or very strict industry trade group specifications, or are naturally consistent in composition. As long as the suppliers' and our own chemical analyses indicate equivalence, our experience is that clinical studies of ingredients from alternate suppliers are unnecessary. We want to reemphasize that strict quality control is necessary and is to be maintained, but that clinical testing is not required in such cases.

SUMMARY

In summary, the range of nutrient intakes which promote good health and well being for infants is well known. Our guidelines are those set forth by the Committee on Nutrition of the Academy of Pediatrics which are based on years of research in the nutritional sciences and infant nutrition. Using ingredients with which we have extensive experience, safe and nutritious infant formulas which conform to these guidelines are readily made. Laboratory tests assure that high standards are met and maintained. Numerous clinical studies of infant formulas have been performed in the last sixty years to advance the state of the art. These have confirmed the nutrient quality and availability of the ingredients of infant formulas and have contributed substantially to progress in the field of infant nutrition. Clinical studies have not been used as quality control checks, nor do we believe they are appropriate for this purpose. I have outlined the levels of clinical investigation of formulas in use, how they are applied to reformulation, and the review and approval process for proposed formulation changes.

We subscribe to the maintenance of comprehensive quality control measures and to the conduct of appropriate clinical investigations when necessary. We want to reassure the FDA and the public that we are committed to carefully reviewing all proposed changes and to considering all important factors before we begin clinical studies with infants.

/md

Senator METZENBAUM. Thank you very much.
The next witnesses are Dr. Cordero and Dr. Woodruff.

STATEMENT OF CALVIN WOODRUFF, M.D., F.A.A.P., AMERICAN ACADEMY OF PEDIATRICS AND JOSE CORDERO, M.D., CENTER FOR DISEASE CONTROL

Dr. WOODRUFF. I am a professor of child health at the University of Missouri, Columbia, and I am representing the Committee on Nutrition, American Academy of Pediatrics, an organization of 22,000 board-certified pediatricians in North America.

I would like to ask my written statement be submitted for the record and would like to summarize a few major points.

Senator METZENBAUM. Your full statement will be included in the record.

Dr. WOODRUFF. There is a need for regulations for minimum and maximum nutrients in infant formulas. The FDA is the most appropriate place in the long run for this type of regulation. The infant formula bill of 1980 would seem to be a good instrument to initiate this process. But the thing that concerns us about putting nutrient levels in the legislation is that a provision for change as scientific knowledge accumulates is most important. We feel that working toward a standard of identity for infant formulas is quite premature at the present time.

We have a few minor points as well. We take exception to the provision that would permit a physician or other appropriate health professional to diagnose metabolic disease. This should be done only by physicians who are trained to make the diagnosis of metabolic disease.

As far as labeling is concerned, the nutrient content should be expected. But the summary of the benefits and risks associated with the use of such product, including endorsement of breast feeding as method of first choice, unless otherwise advised by the physician, we take exception to this particular statement in your bill. Although we encourage breast feeding as optimum nutrition for infants, the Committee on Nutrition has pointed out that women who decide to use formula should not be made to feel guilty if they do not nurse their infants. This should be an educational effort. Further efforts to promote breast feeding should go on. We are not sure that label is the most appropriate place for this particular method. And we are not sure how to summarize the risks and benefits of the food in a concise manner. We have been working with the Infant Formula Council and FDA on the appropriate written and pictorial labeling of infant formula such as the addition of water. This is a problem that we still have, and whether to or not to, and to make it obvious, and in nonlanguage and multiple-language written forms, so there would be no possibility of it being misunderstood, and this is a problem that remains to be solved.

Finally we feel that our recommendations concerning infant formula as far as nutrient requirements are concerned apply to all normal infants regardless of geographical location, and we support the provisions concerning export of adulterated products.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Woodruff follows:]

American Academy of Pediatrics

Testimony

before the

Committee on Labor and Human Resources
Subcommittee on Health and Scientific Research

on

The Infant Formula Act of 1980
S. 2490

Presented by

Calvin Woodruff, M.D., F.A.A.P.

June 12, 1980

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My name is Calvin Woodruff. I am a Professor of Child Health at the University of Missouri-Columbia. I am representing the Committee on Nutrition of the American Academy of Pediatrics, an organization of 22,000 Board-certified pediatricians in North America.

The Committee on Nutrition supports most of the provisions of S. 2490, the Infant Formula Act of 1980. We feel that FDA should establish minimum and maximum standards for the nutrient content of infant formula. The American Academy of Pediatrics has worked with that agency in the past and will continue to do so in the future by making and publishing specific recommendations on infant nutrition. We have testified at hearings held early this year by the FDA on both the content and clinical testing of formulas. The Academy also testified before Representative Waxman's Subcommittee in favor of requiring the Secretary to establish minimal and, where appropriate, maximum levels of nutrients in infant formula rather than to specify them in the bill, despite provisions in the bill for the Secretary to change or revise these standards in the future. We believe that appropriate regulations by the Secretary are the most appropriate way to regulate the infant formula industry. The addition of the section on marijuana trafficking was unfortunate.

We do take exception to the provision, under Section 412(a)(2), which would permit "a physician or other appropriate health professional" to diagnose inborn errors of metabolism (emphasis ours). Diseases such as PKU (phenylketonuria), galactosemia, and Maple Syrup Urine Disease should be diagnosed by a physician who is experienced in these genetic abnormalities, and such diagnoses should not be made by other health professions.

We also wish to comment on the labeling requirements for formulas, especially the requirement in the bill that all formula products provide

> "a summary of the benefits and risks associated with the use of such product including an endorsement of breast feeding as the method of first choice unless otherwise advised by a physician..."

Although the American Academy of Pediatrics encourages breast feeding as the optimum nutrition for infants, the Committee on Nutrition has also pointed out that women who decide to use formula should not be made to feel guilty. While we would urge that educational efforts be strengthened to promote breast feeding, we feel that a label is an inappropriate place for such an endorsement.

Indeed, the issue of appropriate labeling is a complex one. For the last year the Committee on Nutrition has been working with the Infant Formula Council on the problem of appropriate written and pictorial labeling of infant formula regarding the addition of water to concentrated and powdered formulas. Moreover, we are not sure how to summarize the risks and benefits of a food.

We feel that our recommendations concerning infant formula apply to all normal infants regardless of geographical location and we support the provision concerning the export of adulterated products.

Senator METZENBAUM. Thank you, Dr. Woodruff.

There is a rollcall on. I am only going to ask you one question as a consequence so we can still hear Dr. Cordero.

Has the Academy done anything to notify their members about the problem of chloride deprivation, the failure to have sufficient chloride in the formula? Has there been any edification at all for pediatricians by the academy on that subject?

Dr. WOODRUFF. The Committee on Nutrition did not put out a specific notification on this at the time that it happened, but at least one of the scientific articles concerning this was published in our journal, Pediatrics—I would like to correct myself, Mr. Chairman—I think there was a note about this in the Academy's monthly newsletter, so that pediatricians would be alerted. This was after the publicity which came quite early when this was discovered.

Senator METZENBAUM. Thank you very much, Dr. Woodruff. The committee may have some questions for you. I am rushing along because I do not want to miss the rollcall. There are two rollcalls.

Dr. Cordero, would you very briefly tell us the position of the CDC and what CDC has been doing to alert parents to the chloride deficient formula problem, how many phone calls you have received, what you are doing to followup on those phone calls, and how many children, if you know, who had been using them also have expired as a consequence thereof?

Dr. CORDERO. Thank you, Senator.

I would first like to introduce Dr. David Erickson, deputy chief of the birth defects branch.

In trying to answer your questions, the CDC has done several things. First, on August 3 and August 10 in the morbidity and mortality weekly report we summarized our findings on the problem of metabolic alkalosis. This is a weekly CDC publication, and it has wide distribution throughout the country. We also summarized our findings for the international community in the letter to the editor of the Lancet.

CDC also has established a registry of cases of metabolic alkalosis associated with the use of Syntex formulas. We have directed our attention to ascertain cases in many ways. We have contacted all pediatric nephrologists throughout the country. We conducted a survey of all chairpersons of pediatric departments in the country. Twelve new cases were found that way.

Senator METZENBAUM. Dr. Cordero, I want to excuse myself. Dr. Rhonda Friedman, my staff assistant, will conclude the hearing and will ask you some questions on my behalf. Please excuse me, but I do have to go vote.

Dr. FRIEDMAN. Please finish your statement.

Dr. CORDERO. We have received reports of cases from the Food and Drug Administration and manufacturers and physicians throughout the country. At the present time there are 134 cases of metabolic alkalosis in our registry.

Let me explain what we define as a case of metabolic alkalosis. The case is an infant who used a Syntex formula who had documented evidence of a chloride deficiency; that is, a blood test has been performed and a low-chloride level and/or an elevated blood pH were found. We are acutely aware that many infants did not have the benefit of the blood chloride or blood pH test. For this

reason we have kept a registry of infants who had the clinical picture, which is compatible with the diagnosis of metabolic alkalosis.

In that group we have 46 infants, that is a total of 180 cases.

Dr. FRIEDMAN. You said you contacted pediatric nephrologists around the country?

Dr. CORDERO. Yes.

Dr. FRIEDMAN. Do you not think most cases would have been noted by the local pediatrician or family practitioner?

Dr. CORDERO. Yes. If I could finish my testimony, I will answer that question.

We have also planned to study the national impact of the problem. We have signed a contract with the Commission of Professional Hospital Activities to obtain hospital discharge summary data for the years 1977, 1978 and the first three quarters of 1979. These data will provide an estimate of the rate of metabolic alkalosis throughout the Nation and the geographic distribution of cases and other parameters. In collaboration with the National Institute of Health, the Food and Drug Administration and CDC, we have developed a followup study of all infants who develop metabolic alkalosis while using a Syntex formula. This study consists of yearly developmental evaluation and assessment of their metabolic status. This followup study will help to determine any possible long-term effects that may be associated with exposure to Syntex formulas during the first year of life.

That is the end of my summary.

Dr. FRIEDMAN. You said you contacted pediatric nephrologists, and also I think teaching hospitals throughout the country. Would you not think that many of these cases would have shown up at local pediatrician or family practitioners, and have you done anything to try and alert them to this problem?

Dr. CORDERO. Metabolic alkalosis, in the first year of life, is a very complex problem. We believe that most practitioners that are faced with that problem will contact, if not consult, specialists in the area. That was the reason to contact the chairman of the department of pediatrics. As a matter of fact of the 12 cases that we found through that survey, maybe more than half were not admitted to a major university hospital. The department of pediatrics in each respective case knew about them through telephone consults from practitioners of that area.

Dr. FRIEDMAN. Earlier the pilots testified, that they had to insist the electrolyte and blood gases tests be done. The physicians had actually said that the symptoms Brad suffered were not symptoms that normally are present with metabolic alkalosis. Is it not possible there are many more cases that may not have been documented but, in fact, were cases in which children experienced problems as a result of ingesting Neo-Mul-Soy?

Dr. CORDERO. From many letters we have received inquiring about our problems relating to Neo-Mul-Soy and Cho-Free formulas, we have requested over 400 parents to send copies of their medical records. We have reviewed over 100 of them. That is how many we have received so far. We have found one case of documented metabolic alkalosis that we did not know about. Of all other infants, very few actually had the kinds of symptoms that

would be compatible with the symptoms that have been observed in infants who developed metabolic alkalosis.

Dr. FRIEDMAN. Earlier this year there was a television program alerting parents to chloride deficient formula problems. I understand that CDC received several phone calls after that. Parents were concerned.

How many phone calls did you receive?

Dr. CORDERO. Between phone calls and letters, over 3,000.

Dr Friedman. What are you doing to follow these up?

Dr. CORDERO. Well, we classified the inquiries according to the nature of the inquiry. If they requested information, the information was sent to them. If the letter or inquiry stated there was a problem with a child, we requested further information, that is, medical records.

Dr. FRIEDMAN. You followed up with physician or parents?

Dr. CORDERO. Both. Actually we just have done it on an individual basis according to the particular case.

Dr. FRIEDMAN. From those 3,000 inquiries you have not found any other additional cases?

Dr. CORDERO. From 3,000, we requested information on about 400, and of that we found one case.

Dr. FRIEDMAN. How many children who were using Neo-Mul-Soy have died?

Dr. CORDERO. Are you asking any child using Neo-Mul-Soy, regardless of whether it was associated?

Dr. FRIEDMAN. Can you determine if it was associated?

Dr. CORDERO. We know of two cases that children were using Cho-Free and subsequently died. We have requested medical information. We have spoken to doctors that were involved in those cases. In none of the two we could document that their deaths were related to use of the formula. They did have electrolyte testing and blood pH at the time they were using the formula, and they were within normal range.

Dr. FRIEDMAN. In a soon to be published journal article, Drs. Simopoulos and Bartter said:

> The pathophysiologic consequences of the "new" syndrome chloride deprivation in infancy are the subject of the intensive study. They appear to include polydipsia and perhaps an excessive salt appetite and growth retardation, especially retardation of head growth and delayed speech development.

In light of these findings, what is your prognosis for the Neo-Mull-Soy babies?

Dr. CORDERO. I am not familiar at all with the article and I have not had a copy of that, so I would prefer not to comment. I do not know the answer to the question.

Dr. FRIEDMAN. On the basis of your own review and information, what do you think the prognosis is for the babies?

Dr. CORDERO. Well, actually we do not know what exactly is the prognosis. That is the purpose of the followup study that we are conducting in collaboration with NIH.

[The prepared statement of Dr. Cordero follows:]

Statement by

José F. Cordero, M.D.
J. David Erickson, D.D.S., Ph.D.
Bureau of Epidemiology
Center for Disease Control

on

INFANT METABOLIC ALKALOSIS AND SOY-BASED FORMULAS MANUFACTURED BY SYNTEX LABORATORIES, INC.

before the

Subcommittee on Health & Scientific Research
Committee on Labor and Human Resources
U.S. Senate

Dirksen Senate Office Building
Room 1318 - 9:30 AM

June 11, 1980

.rman and Members of the Subcommittee:

appy to be here today to provide testimony on behalf of the Center for
n Control to describe our work regarding the problems associated with
e of soy-based formulas manufactured by Syntex Laboratories. I am
anied by Dr. J. David Erickson who is Deputy Chief of the Birth Defects

y 26, 1979, the Memphis-Shelby County Health Department in Memphis,
see, reported to CDC that three infants were recently admitted to one
al with metabolic alkalosis, a condition characterized by loss of the
blood acidity. These children were initially admitted for evaluation
e of failure to gain weight and loss of appetite. Laboratory tests showed
ey had low blood chloride and potassium levels. All three were using
rand of soy-based formula: Neo-Mull-Soy, manufactured by Syntex
ories, Palo Alto, California.

vestigate the possible association between metabolic alkalosis and the
this formula, CDC conducted a survey of Pediatric nephrologists throughout
ntry during July 27-30, 1979. Through the survey and by other means, 31
ere ascertained. For 27 cases, the type of formula used was known.
ix of the 27 were using Neo-Mull-Soy. Since the formulas manufactured
ey represented about 10% of the soy-based formula market, the finding
ld a strong association between the use of Neo-Mull-Soy and the development
bolic alkalosis. The Food and Drug Administration and the manufacturer
ified of our findings. Since cases were found in many areas of the

country, this problem seemed unlikely to be associated with a particular lot of the formula. Testing of different formula lots by the manufacturer and the Food and Drug Administration (FDA) confirmed that all the formula manufactured in 1979 had levels of chloride below those recommended by the Committee on Nutrition of the American Academy of Pediatrics.

On August 1, 1979, Syntex convened a meeting of pediatric nephrologists who had treated these infants. CDC was represented at the meeting. Tests of the formula by Syntex revealed a very low chloride level. After this meeting, Syntex announced a consumer level recall of all their infant formulas.

CDC's findings were published in the August 3 and August 10 issues of the Morbidity and Mortality Weekly Report. In addition, we summarized our findings for the international medical community in a letter to the editor of The Lancet. The three documents will be submitted for the record.

CDC continued its efforts to ascertain more cases of metabolic alkalosis. A registry of cases was established. Pediatric nephrologists throughout the country were contacted. We also conducted a survey of all chairpersons of Pediatric Departments in the country. Twelve new cases were found. We have also received case reports from the Food and Drug Administration and manufacturers and physicians. At the present time there are 134 cases in our registry.

In collaboration, the National Institutes of Health, the Food and Drug Administration, and CDC have developed a follow-up study of all infants who developed metabolic alkalosis while using a Syntex formula. This study consists of yearly developmental evaluation and assessment of their metabolic status. This follow-up study will help to determine any possible long-term effects that may be associated with exposure to Syntex formulas during the first year of life.

Another study is currently in progress to determine if the soy-based Syntex formulas were associated with other subtle illnesses and/or symptoms. CDC has developed, in the Atlanta area, a follow-up study of infants who have used Neo-Mull-Soy and/or Cho-Free formulas but who did not develop alkalosis. This study is in the final stages. The results will be made public upon completion of the study.

We have also planned to study the national impact of the problem. We have signed a contract with the Commission on Professional Hospital Activities to obtain hospital discharge summary data for the years 1977, 1978, and the first three quarters of 1979. These data will provide an estimate of the rate of metabolic alkalosis throughout the nation and the geographic distribution of cases. These data should be available to us by the end of the summer.

Mr. Chairman, that concludes my testimony. We will be glad to answer any questions from you and other members of the Subcommittee.

Dr. FRIEDMAN. I think that is all. I have no more questions. Thank you very much.

[Whereupon, at 12:15 p.m., the subcommittee recessed, to reconvene subject to the call of the Chair.]

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